UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	Hon. Patti B. Saris

RESPONSE OF THE UNITED STATES OF AMERICA TO DEY DEFENDANTS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF DEY, INC., DEY, L.P., AND DEY L.P., INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules of this Court, the United States hereby submits its Response to Dey Defendants' Statement of Undisputed Material Facts in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment ("Dey SOF"). In the responses that follow, any statement submitted by the Dey defendants that the United States does not dispute is undisputed solely for purposes of the United States' response to Dey's motion for partial summary judgment. The United States reserves the right to dispute any such statement of fact for purposes of trial. *See* LR 56.1. The Relator joins in this Response and aforesaid reservation of rights.

1. Dey, Inc. is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive in Napa, California. Dey, Inc. is the general partner of Dey, L.P. which is engaged in the "development, manufacturing and marketing of prescription drugs used to treat selected respiratory diseases and allergies." (Affidavit of Pamela R. Marrs, dated June 25, 2009 ("Marrs Aff."), ¶ 4.)

The United States' Response: The United States does not dispute Dey's SOF No. 1 and notes that Dey L.P., Inc. is the sole limited partner of Dey L.P.; Dey, Inc. is the general partner

and owns one percent of Dey, L.P. and 100% of Dey, L.P., Inc.; and Dey, L.P., Inc. owns 99% of Dey, L.P. (Henderson Ex. 102, at 58:11 - 59:1) Also, prior to June 30, 1998, Dey, Inc. was known as Dey Laboratories, Inc. See Dey, Inc., Dey L.P., Inc., and Dey, L.P.'s Answer and Defenses to the United States' First Amended Complaint (hereinafter "Answer"), ¶ 12. The three Dey entities are collectively referred to herein as "Dey."

2. Dey was founded in 1978 by four entrepreneurs as a small, start-up company selling generic respiratory medications. (Marrs Aff. ¶ 5.)

The United States' Response: The United States does not dispute Dey's SOF No. 2 and notes that in 1988 Dey was acquired by Lipha Pharmaceuticals, a French corporation that installed one of its employees, Jean-Pierre Termier, as CEO of Dey. (Henderson Ex. 2, at 42:1 - 43:21; Henderson Ex. 102, at 16:7 - 17:6; Henderson Ex. 1, at 20:5 - 21:14) Several years later Lipha changed its name to EMD, Inc. and it, including Dey, was acquired by Merck S.A., a French corporation, which in turn was wholly owned by Merck KGaA, a German pharmaceutical "giant." (Henderson Ex. 1, at 20:5 - 21:14; Henderson Ex. 103, at 6; Henderson Ex. 104) By May 2001, Dey had grown to such size that Dey's CEO Charles Rice characterized Dey to United States Senator Barbara Boxer as "one of the largest private employers in Napa, California." (Henderson Ex. 105.) On or about October 2, 2007, Dey was acquired by Mylan Pharmaceuticals, Inc. (Henderson Ex. 2, at 39:17 - 39:18)

3. Dey's first products were unit-dose sodium chloride solution inhalation solutions ("saline solutions") which the company began to sell in 1978. Dey continues to sell all of these products presently. (Marrs Aff. ¶ 6; Declaration of Sarah L. Reid, dated June 26, 2009 ("Reid Decl."), Ex. 1.)

The United States' Response: The United States does not dispute Dey's SOF No. 3.

4. From 1978 until the late 1980s, Dey's sales, marketing, and distribution facilities were in Texas and its manufacturing plant was in Concord, California. (Marrs Aff. ¶ 7).

The United States' Response: The United States does not dispute Dey's SOF No. 4.

5. During this time period, Dey principally sold saline solutions and other generic respiratory medications in unit dose vials, including acetylcysteine, introduced in 1986, and metaproterenol, introduced in 1987. (Marrs Aff. ¶ 8; Reid Decl., Ex. 1.)

The United States' Response: The United States does not dispute Dey's SOF No. 5.

6. In its first decade, Dey's principal customers were hospitals. (Marrs Aff. ¶9.)

The United States' Response: The United States objects to Dey's SOF No. 6 as ambiguous, irrelevant as outside the time period relevant to this action and as unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1.

7. In the late 1980s, Dey acquired a site in Napa, California. (Marrs Aff. ¶ 10.)

The United States' Response: The United States disputes Dey's SOF No. 7 as it does not accurately reflect the contents of the affidavit to which reference is made.

8. In 1989, Dey moved its manufacturing, sales, and marketing functions to the Napa site, but kept its distribution operations in Texas. (Marrs Aff. ¶ 11.)

The United States' Response: The United States does not dispute Dey's SOF No. 8.

9. Once Dey moved its manufacturing facilities to Napa and received FDA approval, it then had the capacity to manufacture albuterol sulfate in unit dose vials. (Marrs Aff. ¶ 12.)

The United States' Response: The United States does not dispute Dey's SOF No. 9.

10. Albuterol sulfate ("albuterol") is a respiratory inhalation drug that is used for the relief of bronchospasm in patients with reversible obstructive airway disease and acute attacks of bronchospasm. (Marrs Aff. ¶ 13; Reid Decl., Ex. 2; Reid Decl., Ex. 3.)

The United States' Response: The United States does not dispute Dey's SOF No. 10.

11. Dey's principal generic albuterol product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment. (Marrs Aff. ¶ 14.)

The United States' Response: The United States does not dispute Dey's SOF No. 11.

12. Dey submitted an abbreviated new drug application ("ANDA") for albuterol unit dose in the later 1980s. (Marrs Aff. ¶ 15.)

The United States' Response: The United States does not dispute Dey's SOF No. 12.

13. Dey's application was approved in 1992 and in March 1992, Dey became the first pharmaceutical manufacturer to launch a generic albuterol unit dose solution and was the only generic manufacturer in the market for over one year after launch. (Marrs Aff. ¶ 16; Reid Decl., Ex. 4; Reid Decl., Ex. 5, at 169:14-20.)

The United States' Response: The United States does not dispute Dey's SOF No. 13.

14. Not only was Dey's albuterol product the first generic unit dose albuterol to market, it was the first BAC-preservative-free albuterol unit dose solution on the market. (Marrs Aff. ¶ 17; Reid Decl., Ex. 1.)

The United States' Response: The United States does not dispute Dey's SOF No. 14 ex except the statement set forth therein is not supported by Reid Decl., Ex. 1 as Dey posits.

15. Dey became known and respected for the following breakthrough features of its products:

· The replacement of screwtop bottles with the first plastic unit-dose vials;
· Patient-friendly TwistFlex™ vials to reduce cross-contamination;
· BAC-preservative-free.
(Marrs Aff. ¶ 18.)

The United States' Response: The United States disputes Dey's SOF No. 15. On the contrary, these factors were initially important to providers, but "once generic competition came onto the market, it was all about price." (Henderson Ex. 1, at 112:22 - 114:16) Indeed, Ms. Burnham, Dey's Director of Marketing, testified that "spread was very important to our customers. . . it was part of everything that was ever discussed at Dey. . . It wasn't that important at what price the customer bought the product, it was important that they got a – enjoyed a good spread between their acquisition price and their reimbursed price. So it was something that was part of every discussion about pricing, about products, about competition, about market share. It – it was part of every discussion." (*Id.,* at 77:21 - 78:16) Moreover, the testimony upon which Dey's SOF No. 15 is based is hearsay and irrelevant to this action and as such the statement is unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1.

16. With the launch of albuterol, Dey began breaking into other markets, including homecare and to a lesser extent, retail. (Marrs Aff. ¶ 19.)

The United States' Response: The United States does not dispute Dey's assertion in its SOF No. 16 that with the launch of albuterol, Dey began breaking into other markets including

homecare and retail; however, the United States disputes the characterization of the retail market as "to a lesser extent" insofar as it suggests that Dey's retail sales of its unit-dose albuterol were in any manner insignificant, when in fact Dey became a major player in the unit-dose albuterol retail market as set forth more fully in the United States' response to Dey's SOF No. 17 below, the citations to which the United States incorporates herein by reference.

17. Dey did not have a large retail presence, in part, because it did not have a full line of albuterol products available for sale as other larger manufacturers did. (Marrs Aff. ¶ 20.)

The United States' Response: The United States disputes Dey's SOF No. 17. On the contrary, in less than a single year, Dey's Marketing Assistant Robert Ellis was able to enthusiastically report to Dey's sales team and upper management: "It has been quite an exciting year for Dey Laboratories. Due to Albuterol the company has managed to double in size from last year." (Henderson Ex. 38, at DL60046) This success with albuterol was attributable to a significant degree on sales to retailers. Even before the launch of this product, Robert Mozak, Dey's Vice President of Sales and Marketing, set forth in writing to Dey's CEO, COO and CFO Dey's pricing objective with respect to the upcoming launch of Dey's unit-dose albuterol: "TO PROVIDE INCENTIVE TO RETAIL/CHAIN PROVIDERS TO USE DEY'S ALBUTEROL UD [i.e., UNIT DOSE] BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS." (Henderson Ex. 35.) (capitalization in original; bracketed material added for clarification consistent with deposition testimony cited)

After the product launch, Dey developed a marketing piece entitled the Reimbursement Comparison Worksheet for use by Dey's sales force to show its customers, including its retail

and chain customers, how they will make a profit through Medicare and Medicaid reimbursement from the purchase of Dey's unit-dose albuterol. (Henderson Ex. 106, at 76:6 - 77:23, 78:22 - 79:5; Henderson Ex. 1, at 154:5 - 159:11; Henderson Ex. 107, at 52:3 - 53:12; Henderson Ex. 54, at 117:22 - 118:23; Henderson Ex. 61.)

By March 1996, Dey had captured a 35 % market share in the retail pharmacy market. (Henderson Ex. 109) By June, 2000, Dey's unit-dose albuterol had captured 36 % of the unit-dose albuterol retail market, including all branded and generic unit-dose albuterol products, accounting for $179.9 Million in sales dollars for Dey. (Henderson Ex. 110) In this regard, Dey had a far larger retail presence in the unit-dose albuterol retail market than manufacturers such as Sepracor, Ivax, Alpharma and others that together accounted for no more than 5 % of the unit-dose albuterol retail market. (*Id.*)

18. Accordingly, Dey's retail sales for albuterol accounted for a small percentage of sales in the first few years after albuterol launched. (Marrs Aff. ¶ 21.)

The United States' Response: The United States disputes Dey's SOF No. 18. On the contrary, Dey's CEO, Charles Rice, reported in a Sales Commentary dated July 1994 that "Monthly net sales of $8.7 million were ahead of plan and prior year, mostly due to the continuing strong performance of Albuterol." (Henderson Ex. 111; Henderson Ex. 34, at 448:22 - 449:18, 450:20 - 451:3.) By 1995, Dey's albuterol was its top selling product, outselling its next best selling product by over $46 Million in net sales dollars. (Henderson Ex 112.)

19. Dey still manufactures and sells unit dose albuterol although it is not profitable. Currently, there are six other companies that market generic versions of albuterol. (Marrs Aff. ¶ 22; see also Reid Decl., Ex. 6.)

The United States' Response: The United States does not dispute Dey's SOF No. 19 insofar as it states that Dey still manufactures and sells unit-dose albuterol, and the United States agrees that at least six other companies market generic versions of albuterol. However, the United States disputes Dey's assertion that its albuterol is not profitable because it is irrelevant and immaterial to the issues before the Court.

20. In the mid-1990s, Dey tried to expand its albuterol line of products so that it could compete better with the larger manufacturers. (Marrs Aff. ¶ 23.)

The United States' Response: The United States does not dispute that in the mid-1990s, Dey tried to and in fact did expand its albuterol line of products; however, the United States disputes that it did this so that it could compete better with the larger manufacturers. On the contrary, Dey expanded its albuterol line of products in order to capture an even greater share of the albuterol market than it already had. (Henderson Ex. 76; Henderson Ex. 77, at 95:3 - 95:21.)

21. Dey therefore launched its multi dose albuterol product in March 1996 and its metered dose inhaler albuterol product in November 1996. (Marrs Aff. ¶ 24; Reid Decl., Ex. 5, at 176:3-177:14, 177:15-178:17.)

The United States' Response: The United States does not dispute Dey's SOF No. 21 with regard to the launch of Dey's multi-dose albuterol product but disputes the indicated month of the launch of Dey's metered dose inhaler albuterol product because it contradicts the information set forth in Dey's SOF No. 46 and the related information set forth in the Declaration of Lauren

J. Stiroh, Ph.D. dated June 25, 2009, as well as the faxed memorandum from Dey CEO Charles Rice to Dey's parent company dated January 9, 1996 indicating that the MDI was launched in January 1996. (Henderson Ex. 68.)

22. Dey did not manufacture either of these products, but purchased them from other manufacturers. (Marrs Aff. ¶ 25.)

The United States' Response: The United States does not dispute Dey's SOF No. 22.

23. When Dey entered the multi dose albuterol market, there were already a number of competitors selling the same product. (Marrs Aff. ¶ 26.)

The United States' Response: The United States does not dispute Dey's SOF No. 23.

24. Dey stopped selling multi dose albuterol in mid-2003. (Marrs Aff. ¶ 27.)

The United States' Response: The United States does not dispute Dey's SOF No. 24.

25. When Dey entered the metered dose inhaler market, there were already a number of competitors selling the same product. (Marrs Aff. ¶ 28.)

The United States' Response: The United States does not dispute Dey's SOF No. 25 but notes that by fax memorandum dated January 9, 1996, Dey's CEO Charles Rice reported to Dey's parent company that "The albuterol MDI launch has thus far exceeded our expectations, over $1 million in sales after five days on the market! And many of the wholesaler orders are yet to be processed." (Henderson Ex. 68.)

26. Dey stopped selling metered dose inhaler in early 2003. (Marrs Aff. ¶ 29.)

The United States' Response: The United States does not dispute Dey's SOF No. 26.

27. In addition to albuterol, Dey was also pursuing opportunities to launch other generic respiratory inhalation solutions in the late 1980s and early 1990s. (Marrs Aff. ¶ 30.)

The United States' Response: The United States does not dispute Dey's SOF No. 27.

28. Dey thus submitted an ANDA for cromolyn sodium, which was the next generic inhalation solution coming off patent. (Marrs Aff. ¶ 31.)

The United States' Response: The United States does not dispute Dey's SOF No. 28.

29. Cromolyn sodium ("cromolyn") is a prophylactic respiratory inhalation drug used to treat patients with bronchial asthma. Dey's generic cromolyn product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment. (Marrs Aff. ¶ 32; Reid Decl., Ex. 7.)

The United States' Response: The United States does not dispute Dey's SOF No. 29.

30. Dey launched its cromolyn product in May 1994. (Marrs Aff. ¶ 33; Reid Decl., Ex. 5, at 170:4-171:14.)

The United States' Response: The United States notes that the indicated month of the launch of Dey's cromolyn product contradicts the information set forth in Dey's SOF No. 46 and the related information set forth in the Declaration of Lauren J. Stiroh, Ph.D. dated June 25, 2009.

31. As with unit dose albuterol, Dey was the first generic cromolyn on the market. (Marrs Aff. ¶ 33.)

The United States' Response: The United States does not dispute Dey's SOF No. 31.

32. Dey stopped manufacturing cromolyn in February 2008 as it was unable to sustain a profit on sales. (Marrs Aff. ¶ 35.)

The United States' Response: The United States does not dispute Dey's SOF No. 32 insofar as it states when Dey stopped manufacturing cromolyn; however, the United States disputes the remainder of the statement because it is irrelevant and immaterial to the issues before the Court.

33. Currently, there are at least seven companies that sell generic versions of cromolyn. (Marrs Aff. ¶ 34; Reid Decl., Ex. 8.)

The United States' Response: The United States does not dispute Dey's SOF No. 33.

34. Ipratropium bromide ("ipratropium") is a respiratory inhalation drug used for the maintenance treatment of bronchospasms associated with Chronic Obstructive Pulmonary Disease ("COPD"), which is a term used to describe a number of airway diseases, including both chronic bronchitis and emphysema. (Marrs Aff. ¶ 37; Reid Decl., Ex. 9.)

The United States' Response: The United States does not dispute Dey's SOF No. 34.

35. Ipratropium is classified as an anticholinergic bronchodilator because it works by preventing the bronchial smooth muscle from constricting. (Marrs Aff. ¶ 37; Reid Decl., Ex. 10.)

The United States' Response: The United States does not dispute Dey's SOF No. 35.

36. In January 1997, Dey launched a sterile generic unit dose ipratropium bromide solution. (Marrs Aff. ¶ 36; Reid Decl., Ex. 5, at 174:13-175:11; Reid Decl., Ex. 11.)

The United States' Response: The United States does not dispute Dey's SOF No. 36.

37. Dey's generic ipratropium product is a unit dose liquid solution that is administered via a nebulizer, which is a piece of durable medial equipment. (Marrs Aff. ¶ 38.)

The United States' Response: The United States does not dispute Dey's SOF No. 37.

38. Dey continues to sell ipratropium at a close to break even profit level. (Marrs Aff. ¶ 39.)

The United States' Response: The United States disputes Dey's SOF No. 38 because it is irrelevant and immaterial to the issues before the Court.

39. Currently, there are at least seven other companies that sell generic versions of ipratropium. (Marrs Aff. ¶ 39; Reid Decl., Ex. 12.)

The United States' Response: The United States does not dispute Dey's SOF No. 39.

40. By the late 1990s, with increased competition in the generic markets for albuterol, cromolyn, and ipratropium and the quickly eroding profit margins on those drugs as well as the limited number of respiratory drugs delivered via nebulization coming off patent in future years, Dey decided to switch its business model to focusing on developing, manufacturing and selling branded inhalation solutions. (Marrs Aff. ¶ 40.)

The United States' Response: The United States disputes Dey's SOF No. 40 because it is irrelevant and immaterial to the issues before the Court. The United States further disputes Dey's SOF No. 40 because Dey's CEO, Charles Rice, explained in a memorandum in September 1997 regarding Dey's Strategic Planning Meeting scheduled for later that month that, "Prices of newer products are providing marvelous margins, better than expected, and prices of older

products still result in excellent margins overall, that is, for generic products." (Henderson Ex. 113, at DL-TX-0162074)

41. Dey launched two branded inhalation solutions, AccuNeb and DuoNeb, in 2001. (Marrs Aff. ¶ 41.)

The United States' Response: The United States disputes Dey's SOF No. 41 because it does not relate to any of the drugs at issue and because it is irrelevant and immaterial to the issues before the Court.

42. With the launch of these branded products, Dey's marketing and sales efforts were almost entirely focused on promoting Dey's brands instead of its generics. (Marrs Aff. ¶ 42.)

The United States' Response: The United States disputes Dey's SOF No. 42. Dey fails to explain what it means when it says that its marketing and sales efforts were "almost entirely" focused on brands instead of generics, to what extent marketing and sales efforts for its generic products were reduced and how this may be relevant to the issues before the Court. As such, the United States disputes Dey's SOF No. 42 because it is irrelevant and immaterial to the issues before the Court.

43. The First Amended Complaint in this action ("Am. Compl.") alleges claims against Dey arising from reimbursement by Medicare and Medicaid programs to providers for dispensing varying dosages, concentrations, and sizes of Dey's albuterol sulfate, cromolyn sodium, and ipratropium bromide (the "Subject Drugs"). (Reid Decl., Ex. 13, at ¶ 29.)

The United States' Response: The United States disputes Dey's SOF No. 43 because Dey therein purports to characterize the claims set forth in The United States' First Amended

Complaint ("Complaint") in a manner that wholly bypasses its unlawful conduct giving rise to this action in (a) knowingly causing to be presented false or fraudulent claims for payment or approval to the United States for drugs listed in paragraph 29 of the Complaint for reimbursement that was substantially higher than providers' actual acquisition costs for those drugs and based upon reported prices supplied by Dey that were fraudulently inflated, (b) knowingly using the spread as an unlawful inducement in violation of the anti-kickback statute causing resulting false claims to be submitted, (c) knowingly making, using or causing to be made or used false records or statements to cause false or fraudulent claims to be paid or approved by the United States, and (d) by obtaining monies, and by thus being unjustly enriched, as a result of its violations of federal and state law. The Complaint is the best evidence of its contents and the allegations set forth therein.

44. All of the Subject Drugs are generic drugs. (Marrs Aff. ¶ 46.)

The United States' Response: The United States does not dispute Dey's SOF No. 44.

45. The Subject Drugs are sold under a number of National Drug Codes (NDCs). NDCs are 11-digit codes that uniquely identify the drug by manufacturer, active ingredient, and package size. If the packaging of a drug is changed, new NDCs must be assigned; these are often referred to as successor NDCs. (Reid Decl., Ex. 13, at ¶ 29; Reid Decl., Ex. 14, at ¶ 29; Marrs Aff. ¶ 48.)

The United States' Response: The United States does not dispute Dey's SOF No. 45.

46. The following are the NDCs for the Subject Drugs with date of first and last shipment date as applicable:

Subject Drug	Formulation	Strength/ Package Size	NDC	First Shipment Date	Last Shipment Date
Albuterol Sulfate	metered dose inhaler	17 g	49502-0303-17	Q1 1996	Q2 2000
Albuterol Sulfate	metered dose inhaler	17g, 90 mcg	49502-0333-17	Q1 2000	Q1 2003
Albuterol Sulfate	MDI refill	17g	49502-0303-27	Q4 1996	Q2 2000
Albuterol Sulfate	MDI refill	17g	49502-0333-27		
Albuterol Sulfate	multi dose solution	.5%, 20 ml	49502-0196-20	Q1 1996	Q1 2000
Alburterol Sulfate	multi dose solution	.5%, 20 ml	49502-0105-01	Q2 1999	Q3 2003
Alburterol Sulfate	unit dose solution	.083%, 3 ml, 25s	49502-0697-03	Q1 1992	Q2 2004
Albuterol Sulfate	unit dose solution	.083%, 3ml, 25s	49502-0697-24	Q1 2004	current
Albuterol Sulfate	unit dose solution	.083%, 3ml, 30s	49502-0697-33	Q4 1993	Q1 2004
Albuterol Sulfate	unit dose solution	.083%, 3ml, 30s	49502-0697-29	Q1 2004	current
Albuterol Sulfate	unit dose solution	.083%, 3ml, 30s	49502-0697-30	Q1 2005	current
Albuterol Sulfate	unit dose solution	.083%, 3ml, 60s	49502-0697-60	Q2 1992	Q3 2004
Albuterol Sulfate	unit dose solution	.083%, 3ml, 60s	49502-0697-61	Q1 2004	current
Cromolyn Sodium	unit dose solution	20 mg, 2ml, 120s	49502-0689-12	Q2 1994	Q1 2004

Subject Drug	Formulation	Strength/ Package Size	NDC	First Shipment Date	Last Shipment Date
Cromolyn Sodium	unit dose solution	20 mg, 2ml, 60s	49502-0689-02	Q1 1994	Q3 2004
Cromolyn Sodium	unit dose solution	20 mg, 2ml, 60s	49502-0689-61	Q1 2004	Q1 2008
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-03	Q1 1997	Q1 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-24	Q1 2004	Q2 2006
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-26	Q2 2006	current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-33	Q3 1997	Q1 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-29	Q1 2004	Q3 2005
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-31	Q2 2005	current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-30	Q1 2005	current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-60	Q1 1997	Q2 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-61	Q1 2004	Q3 2008
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-62	Q2 2005	current

(Reid Decl., Ex. 13, at ¶ 29; Declaration of Lauren J. Stiroh, Ph.D., dated June 25, 2009 ("Stiroh Decl."), ¶ 5.)

The United States' Response: In general the United States does not dispute Dey's SOF No. 46, except as follows. Dey does not provide support for its assertion concerning the "First

Shipment Date," and Dey's sales transaction data does not correspond to certain of the "First Shipment Dates" shown in the table. Specifically, the First Shipment Date for 49502-0333-17 is Q1 2000, but Dey's transaction data shows that the first sales occurred in Q3 2000. The First Shipment Date for 49502-0105-01 is Q2 1999, but Dey's transaction data shows that the first sales occurred in Q2 1999. The First Shipment Date for 49502-0689-02 is Q1 1994, but Dey's transaction data shows that the first sales occurred in Q2 1994. The United States further that certain factual statements therein concerning the quarters in which Dey launched its metered dose inhaler product and cromolyn product contradict the factual assertions concerning such launch dates set forth in Dey's SOF Nos. 21 and 30 as well as the testimony of Dey by its corporate designee Pamela Marrs in support of those statements.

47. Dey sells the Subject Drugs to various classes of customers, including wholesalers, retail generic distributors, chain pharmacies, independent pharmacies, homecare pharmacies, hospitals, and long term care facilities. (Reid Decl., Ex. 5, at 35:11-36:6.)

The United States' Response: The United States does not dispute Dey's SOF No. 47.

48. Dey sells its drugs through two primary distribution channels – direct sales and indirect sales. (Reid Decl., Ex. 5, at 90:11-91:8.)

The United States' Response: The United States does not dispute Dey's SOF No. 48.

49. In a direct sale, Dey invoices its customer for a product and then ships the product directly from Dey's distribution center to that customer. (Reid Decl., Ex. 5, at 90:11-16.)

The United States' Response: The United States does not dispute Dey's SOF No. 49.

50. All sales to wholesalers as well as all sales to purchasers who can take delivery at their own distribution center are direct sales. (Reid Decl., Ex. 5, at 90:11-91:4.)

The United States' Response: The United States disputes Dey's SOF No. 50 which is not supported by the cited testimony of Dey through its corporate designee, Pamela Marrs except as to sales to wholesalers.

51. An indirect sale can be a sale that takes place between Dey's wholesale customer and one of Dey's contract customers who does not take direct delivery of the product. (Reid Decl., Ex. 5, at 90:11-91:8, 103:6-104.)

The United States' Response: The United States does not dispute Dey's SOF No. 51.

52. In an indirect sale with a contract, Dey negotiates a contract price with an indirect customer that will ultimately purchase Dey's product from a wholesaler. (Reid Decl., Ex. 5, at 90:11-91:1; 91:5-8; Reid Decl., Ex. 15, at 456:5-457:7.)

The United States' Response: The United States does not dispute Dey's SOF No. 52.

53. The contract price sets forth the price between Dey and the indirect customer, not the price between the indirect customer and the wholesaler. (Reid Decl., Ex. 5, at 99:18-100:5.)

The United States' Response: The United States disputes Dey's SOF No. 53. Dey's Senior Manager of Contracts, Russell Johnston, testified that "the contract price is negotiated between the pharmaceutical company and the buyer, the end user. The wholesaler agrees to honor that price. And so when the wholesaler sells a carton of or a unit of that product to that end user at a contract price that's less than WAC, they file electronically what's called a chargeback. And it is an electronic transmission to the pharmaceutical company. The

pharmaceutical company then – their system will issue a response, an electronic transmission, which provides a credit to the wholesaler, the difference between the WAC price, wholesale acquisition cost, and the contract price." (Henderson Ex. 10, at 106:22 - 107:14) In the situation described by Mr. Johnston, then, the wholesaler sells the product to Dey's indirect customer at the contract price negotiated between Dey and its indirect customer, contrary to the assertion set forth in Dey's SOF No. 53. Testimony of representatives of the major wholesalers McKesson and Cardinal Health establishes that major wholesalers honor the indirect contract price. *See* United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey ("US-D-SOF") ¶¶ 39, 40.

54. Wholesalers also make indirect sales to customers with no contracts with Dey. In indirect sales where there is no contract with Dey, Dey has no visibility into the price paid by the wholesaler's customer. (Reid Decl., Ex. 16, at 104:10-12.)

The United States' Response: The United States disputes Dey's attempt to confuse the term "indirect sales" and disputes Dey's claim of ignorance concerning prices at which retail classes of trade purchase Dey's drugs from wholesalers. First, Dey's employees have consistently described "indirect sales" as sales pursuant to "indirect contracts," i.e., sales pursuant to contracts negotiated between Dey and an "indirect customer" who acquires the Dey product through a wholesaler. Such indirect sales are always lower than WAC (see Response to Dey SOF ¶ 73, below; Henderson Ex. 10, at 104:19 - 105:10) and Dey therefore pays "chargebacks" to the wholesaler for the difference between the WAC and the contract price. The wholesalers honor the indirect contract price. US-D-SF ¶¶ 39-40; Henderson Ex. 10, at 106:20 - 107:3) Dey pays an administrative fee to the wholesaler that allows the wholesaler to make a

profit from servicing the indirect contract. US-D-SF ¶ 41. Dey tracks the chargeback transactions in relation to the indirect contracts in Dey's indirect sales transaction data. As a result, Dey has direct knowledge of the net prices paid by various classes of trade, including retail pharmacies, to Dey for Dey's products. In contrast, when a wholesaler purchases product directly from Dey and subsequently sells the product to a retail customer who is not purchasing pursuant to an indirect contract, this is not an "indirect sale" or "indirect contract" in Dey's parlance, and Dey does not receive chargeback data on such sales. Dey does not know the exact prices paid by those purchasers, and Dey does not have sales transaction data concerning those sales. (*Id.*)

Second, although Dey does not know the exact prices paid by wholesale customers who do not purchase through indirect contracts negotiated with Dey, Dey nonetheless knows that those prices are competitive with, and therefore close to, the prices that Dey negotiates in its indirect contracts with retail customers. (Henderson Ex. 17, at 291:18 - 292:16.) Dey knows that wholesaler margins are very small. (Henderson Ex. 14); Henderson Ex. 15, at 226:20 - 227:2.)

55. In 1984, Congress enacted the Hatch-Waxman Act in an effort to encourage the use of generic drugs in the United States and to lower the cost of prescription drugs for American consumers through generic competition. (Reid Decl., Ex. 17; Declaration of W. David Bradford, dated June 25, 2009 ("Bradford Decl."), ¶¶ 3, 5, 6.).

The United States' Response: Insofar as Dey in its SOF No. 55 purports to render as a statement of fact the legislative purpose and history of the Hatch-Waxman Act, the United States disputes the proposal that the declaration of Dey's proposed expert sufficiently establishes the

legislative history of the statute or its intent. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

56. Many states' Medicaid agencies have adopted drug formularies and mandatory generic substitution rules requiring the use of generics in the place of brands when available. (Bradford Decl. ¶ 12.)

The United States' Response: The United States does not dispute Dey's SOF No. 56. Indeed, by 2006, 41 state Medicaid programs had mandatory generic substitution requirements. (Henderson Ex. 114, at 2.)

57. As a generic drug manufacturer, Dey offers pharmaceutical products that are therapeutically equivalent to branded products. To be considered a generic equivalent to the brand drug and substitutable for the brand under generic substitution laws, a generic drug must have the same active ingredient, dosage strength and form, and route of administration as the equivalent brand drug. (See, e.g., Reid Decl., Ex. 18, at vii-viii.)

The United States' Response: The United States does not dispute the first sentence of Dey's SOF No. 57, but disputes the accuracy of Dey's purported definition of therapeutic equivalence in the second sentence of its SOF No. 57 because it does not accurately set forth the definition of therapeutic equivalence contained in the section of the FDA publication cited by Dey.

58. The entry of generic manufacturers leads to increased competition, and as a result, prices decline. This prediction has been confirmed by many studies that show rapid decline in prices after the generic entry. (Bradford Decl. ¶¶ 8, 9, 10.)

The United States' Response: The United States does not dispute Dey's SOF No. 58 as a general proposition, but notes that Dey cites Paragraph 10 of the declaration of its proposed

expert W. David Bradford in support of that proposition. In that paragraph of his declaration, Dr. Bradford says: "Intense competition and the resulting rapid decline in price is not only widely understood, but also reflected in published WAC prices for Dey's subject drugs." In so noting, however, both Dr. Bradford and Dey fail to disclose Dey's practice of lowering its customers' contract prices when Dey lowers its reported WACs in order to maintain the spread advantage of Dey's reported prices for its customers, as explained by Dey's CEO, Charles Rice:

> Q. If Dey reduces its WAC but then takes action with a customer to preserve that relationship to maintain the same spread for the customer based upon the new WAC, isn't that the same as marketing the spread?
> A. Absolutely not. How would you presume it to be marketing the spread?
> Q. Well --
> A. If -- if the WAC was raised and the price to the customer was lowered, that would be marketing the spread. You're trying to enhance sales in that case by creating an artificial spread. Or if a customer has a pricing situation whereby the WAC or AWP in this -- in any case is higher, and yet the market price or the price to the customer or the contract price is reduced, that's marketing the spread.
> Here we're not marketing the spread.
> We're acting on behalf of the customer. We're changing our WAC, which the customer has no control over. Therefore, we adjust our contract price to maintain the same spread which is already lower than our competition.

(Henderson Ex. 83, at 202:2 - 202:23.)

59. Government reports and studies also find that the generic market is characterized by intense competition and that prices fall as generic entry increases. (See Reid Decl., Ex. 19; Reid Decl., Ex. 20, at 26; Reid Decl., Ex. 21, at xii–xiii; Bradford Decl. ¶ 9.)

The United States' Response: The United States does not dispute Dey's SOF No. 59 as a general proposition, but notes that Dey cites Paragraph 9 of the declaration of its proposed expert W. David Bradford in support of that proposition. However, in that paragraph of his declaration, Dr. Bradford incorrectly cites to specific pages of a 2003 CBO report in support of a factual assertion that is not located on or supported by the pages cited.

60. Because of the savings that generics confer, payers, including Medicare and Medicaid, have put in place programs to encourage substitution of generic drugs. (Bradford Decl. ¶ 11.)

The United States' Response: The United States does not dispute Dey's SOF No. 60 as a general proposition, but notes that Dey cites paragraph 11 of the declaration of its proposed expert W. David Bradford in support of that proposition. In that paragraph of his declaration, however, Dr. Bradford goes much further than the statement in Dey's SOF No. 60 and posits that spreads between reimbursement amounts and actual acquisition prices are necessary and intended by Medicare and Medicaid programs to encourage pharmacies to dispense generic drugs rather than brand drugs when generics enter the marketplace. In so stating, however, Dr. Bradford provides no empirical support for his assertion and wholly ignores the fact that by 2006, 41 state Medicaid programs had mandatory generic substitution requirements, rendering such economic incentives unnecessary. (Henderson Ex. 114, at 2.)

61. Before a pharmacy will have the incentive to substitute a less expensive generic for a more expensive brand, the pharmacy must earn at least as large of a dollar margin on the generic as on the brand. A mathematical consequence of this is that percentage margins for generic drugs will be generally higher than those on brand-name drugs. (Bradford Decl. ¶ 13.)

The United States' Response: The United States disputes Dey's SOF No. 61. It ignores the fact that by 2006, 41 state Medicaid programs had mandatory generic substitution requirements, rendering such economic incentives unnecessary. (Henderson Ex. 114, at 2.) Thus, in order to encourage pharmacies to substitute a generic for a brand drug, Medicare and Medicaid do not need to match the dollar margin on the brand; they can simply require that pharmacies dispense the generic regardless of the dollar margin. In fact, some state Medicaid programs have taken additional measures to encourage generic drug utilization. These include placing generics on the preferred drug list and setting higher copayments for brand name drugs. (*Id.,* at 3.) Dr. Bradford's suggestion that States encourage manufacturers to report falsely inflated prices because the States believe pharmacy providers will violate mandatory generic substitution laws is novel, and disputed. It is not necessary to encourage falsity in order to discourage violations of the law.

62. Thus dollar margins and spreads on generic prescription appear exaggerated when presented in percentage terms. The more relevant comparison from the perspective of the generic substitution is the dollar margin between the brand and generic prescription. (Bradford Decl. ¶ 13.)

The United States' Response: See response No. 61 above. Medicare and Medicaid do not need to match the dollar margin on the brand in order to encourage pharmacies to substitute a generic for a brand drug; they can simply require that pharmacies dispense the generic regardless of the dollar margin.

63. The average prescription payment for a brand albuterol sulfate in 2000 in Massachusetts was $135.40. Similarly the average prescription payment for a generic (Dey) albuterol

sulfate in 2000 in Massachusetts was $21.50. For the brand prescription, $13.50 reflects a 10% margin. (Bradford Decl. ¶ 13.)

The United States' Response: The United States disputes Dey's SOF No. 63 because it is based upon purported facts set forth in paragraph 13 of the declaration of Dey's proposed expert W. David Bradford, but Dr. Bradford cites to no evidentiary foundation, source or documentation for the facts that he sets forth therein, which are necessarily hearsay and inadmissable. Moreover, Dey's SOF No. 63, including but not limited to the unexplained calculation of 10 % of the brand price for albuterol in Massachusetts in 2000, is irrelevant and immaterial to this action and as such the statement is unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Indeed, Dey's calculation of 10 % of the brand price for albuterol in Massachusetts in 2000 fails to explain, excuse or justify its unlawful submission of inflated WAC and AWP prices to pricing compendia with the knowledge and intent that the Medicare and Medicaid programs would use such prices in determining the reimbursement for Dey's generic albuterol, cromolyn sodium and ipatropium bromide throughout the period relevant to this action.

64. If a payer wants the pharmacy to substitute a generic it will need to match the dollar margin on the brand. The same $13.50 reflects a 63% margin on the generic prescription. Furthermore, $13.50 reflects a 169% "spread" on the generic prescription. (Bradford Decl. ¶ 13.)

The United States' Response: The United States disputes Dey's SOF No. 64. Contrary to Dey and its proposed expert's unsupported assertion that a payor will need to match the dollar margin on the brand in order to incentivize the pharmacy to substitute a generic, a payor can instead incentivize a pharmacy to substitute a generic by making such substitution mandatory and

nondiscretionary. Massachusetts has done this, Mass. Gen. L. ch. 112 § 12D, as have, 41 other States. See Response No. 61 above. Moreover, Dey and its proposed expert miscalculate even the purported spread on a generic prescription for albuterol in Massachusetts in 2000; assuming its unattributed underlying numbers to be correct, the spread would not be 169 % but would rather be 163 %. Either way, Dey's calculation of such a spread fails to explain, excuse or justify its unlawful submission of inflated WAC and AWP prices to pricing compendia with the knowledge and intent that the Medicare and Medicaid programs would use such prices in determining the reimbursement for Dey's generic albuterol, cromolyn sodium and ipatropium bromide throughout the period relevant to this action.

65. In the above example, switching to the generic drug results in a savings of $113 for Massachusetts Medicaid. To achieve that savings, Massachusetts must keep the pharmacy from losing revenue in the process. (Bradford Decl. ¶ 13.)

The United States' Response: The United States disputes Dey's SOF No. 65. Dey and its proposed expert assert that Massachusetts must keep a pharmacy from losing revenue in order to incentivize the pharmacy to substitute a generic, but in doing so they ignore the mandatory generic substitution requirement imposed by the Massachusetts Medicaid program. Mass. Gen. Laws, Ch. 112, § 12D (2009). Thus, the reporting of falsely inflated prices does not save Massachusetts anything; it causes overpayments to providers.

66. At launch, pricing for a generic, like Dey's albuterol, is set in relationship to the brand AWP. (Reid Decl., Ex. 5, at 129:22-130:11.)

The United States' Response: The United States disputes Dey's SOF No. 66, which is stated as if it is a general truth, whereas in fact it simply states Dey's chosen practice as evidenced by the deposition citations cited therein, which state that Dey followed what it was told by First DataBank. Yet in its SOF No. 68, Dey admits that it was informed by First DataBank that in order for a drug to be listed as a generic by First DataBank, a drug's AWP must be "at least" 10 % lower than the brand. There was no requirement conveyed to Dey by anyone that Dey set its AWP at any level other than the true amount of its average wholesale price, yet Dey chose to set its AWPs at launch at 10 % below the brand AWP, the highest possible amount that it understood would still qualify the drugs to be listed as generics by First DataBank. (Henderson Ex. 2, at 131:8 - 132:4.) More tellingly, however, First DataBank testified through its corporate designee Patricia Kay Morgan, its Manager of Editorial Services, that First DataBank was unaware of any such "10 % Rule" by which First DataBank was said to have distinguished between brand drugs and generics. (Henderson Ex. 115, at 58:24 - 59:23) There is no "industry practice" of setting generic AWPs at ten percent below the brand AWP. (Henderson Ex. 116, ¶¶ 11-16.)

67. Dey's practice of establishing AWPs for the Subject Drugs at a percentage lower than the therapeutically equivalent brand AWPs was consistent with what Dey believed to be the industry practice. (Reid Decl., Ex. 22, at 460:2-8.)

The United States' Response: The United States disputes Dey's SOF No. 67 and incorporates by reference its response to Dey's SOF No. 66 as if fully set forth herein at length. Further, the self-serving testimony of Ms. Marrs concerning Dey's "belief" is belied by the

voluminous evidence concerning Dey's true motivation behind its price-reporting practice. See US-D-SF ¶¶ 81-158.

68. Ed Edelstein of First Databank informed Dey that a generic AWP must be at least 10% lower than the corresponding brand AWP in order to be listed as such by First DataBank. (Reid Decl., Ex. 5, at 129:22-131:14; Reid Decl., Ex. 23, at 731:17-24.)

The United States' Response: Undisputed.

69. According to Patricia Kay Morgan, former Manager of Editorial Services at First DataBank, there was a "perception in the industry" that a generic drug had to be priced at least 10 percent less than the brand price. (Reid Decl., Ex. 24, at 21:4-18.)

The United States' Response: The United States objects to Dey's SOF No. 69 because it is based on inadmissible hearsay and lacks proper foundation.

70. Accordingly, Dey set its AWPs for its generic drugs at approximately 10% of the brand AWP and left that price unchanged. (Reid Decl., Ex. 5, at 131:8-132:12.)

The United States' Response: The United States disputes Dey's SOF No. 70. Dey changed its AWP when it was to its competitive advantage, but never to reflect the actual average wholesaler prices of its drugs. For example, Dey raised its reported AWP for its drug Euthyrox in order to bring its AWP spread in line with its competitors. (Henderson Ex. 34, at 430:6 - 431:8) Nineteen additional examples of Dey changing the AWPs on its products can be seen in the letter from Dey's Executive Vice President of Sales and Marketing Robert Mozak dated July 18, 2000. (Reid Decl. Ex. 25.) And Dey lowered the AWP on its generic albuterol product in the third quarter of 1994. (Henderson Ex. 19 (Platt Decl., Graphs A4, A6).)

71. Dey then set its WAC price for its generics as a percentage off Dey's AWP. (Reid Decl., Ex. 5, at 144:1-4; Reid Decl., Ex. 22, at 486:6-487:6.)

The United States' Response: The United States does not dispute that Dey did not set its WAC based upon wholesalers' actual acquisition costs for its drugs.

72. Figures A through K of Stiroh Declaration show Dey's WACs relative to its AWPs, AMPs, and FSS data. (Stiroh Decl., Figures A-K for prices through 2004; see confidential Figures A-K for prices through first quarter 2007.)

The United States' Response: The United States disputes Dey's SOF No. 72 because the comparisons of data depicted in Figures A through K of the Stiroh Declaration are irrelevant and immaterial to the issues before the Court.

73. WAC is Dey's invoice price to wholesalers. (Reid Decl., Ex. 5, at 75:22-76:3, 144:21-145:1; Reid Decl., Ex. 22, at 537:9-15; Reid Decl., Ex. 16, at 29:6-12, 31:14-16; Reid Decl., Ex. 15, at 501:2-17; Reid Decl., Ex. 25, at DL-0050108.)

The United States' Response: The United States disputes Dey's SOF No. 73. Dey's witnesses repeated this definition like a mantra. For instance, Dey's Senior Manager of Contracts, Russell Johnston, testified as follows:

> And just to go back to the basics on WAC. WAC is or W-A-C stands for wholesaler acquisition cost, correct?
> A. Wholesale acquisition cost.
> Q. Okay. And that's the cost at which a wholesaler buys a drug from a manufacturer such as Dey, right?
> A. And that is the price that -- speaking for Dey, which is my experience -- is the price

> we invoice a wholesaler for the purchase of any Dey product.
> Q. So put another way, WAC is the price at which you, Dey, sell to a wholesaler such as AmeriSource, correct?
> A. And it's defined as the invoice price that we invoice a wholesaler when they purchase any Dey product.
> Q. When you say it's defined, where is it defined like that?
> A. Well, we were just reading one of --
> Q. Oh, it's defined by Dey in that way?
> A. Well, I think that that's been our response and my response throughout. And I can certainly read it again if you'd like.

(Henderson Ex. 17, at 500:22 - 502:2)

But in fact it was Dey's practice to ensure that Dey's actual prices were nearly always below it's reported WAC's. Dey specifically designed its WAC for any given drug to be above the highest contract price for that drug. (Henderson Ex. 54, at 320:6 - 320:12.) Dey's WACs were not only set at a price higher than any contract price for the drug at issue, they were set higher than Dey's prices to retail distributors. And they were set higher than any price paid by a customer directly to Dey for that drug. (Henderson Ex. 40, at 75:10 - 76:7, 79:1 - 79:4.) Moreover, Dey generally waited until its reported WAC prices were 40 - 50 % above market prices before it would report a lower WAC. (Henderson Ex. 117.)

74. As prices for the Subject Drugs decline over time, Dey reduces the WAC for those drugs. (Reid Decl., Ex. 26, at 662:6-12; Reid Decl., Ex. 26, at 823:13-19; Reid Decl., Ex. 5, at 136:16-21; Reid Decl., Ex. 27, at 8, 28.)

The United States' Response: The United States does not dispute Dey's SOF No. 74, except as to the circumstances described in the US-D-SF ¶¶ 68-71. The United States further

notes that it has been Dey's practice to wait until its reported WAC prices are 40 - 50 % above market prices before it reports a lower WAC. (Henderson Ex. 117.)

75. Dey regularly updated its WACs in a manner that directly reflected underlying pricing activity. (Reid Decl., Ex. 28, at 372:11-20; Reid Decl., Ex. 29, at DL-TX-0092446-50.)

The United States' Response: The United States disputes Dey's SOF No. 75. On May 30, 1995, Dey reported inflated WACs to FDB that clearly did not reflect underlying pricing activity. See US-D-SF ¶¶ 68-71, 80. Indeed, Dey's Director of Marketing, Helen Burnham Selenati, stated in an internal Dey memorandum dated that same day: "WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement. Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement." (Id. ¶¶ 122-128.) In other circumstances, it has been Dey's practice to wait until its reported WAC prices are 40 - 50 % above market prices before it reports a lower WAC. (Henderson Ex. 117.) Moreover, Dey's WACs never directly reflect its underlying pricing activity. The WAC prices that Dey reports for publication do not include the effect of chargebacks or discounts such as rebates, prompt pay discounts, administrative fees, and other types of price concessions. (Henderson Ex. 17, at 468:3 - 468:11.)

76. Throughout the relevant time period, Dey reported WACs for the Subject Drugs to pricing compendia such as First DataBank, RedBook, and Medispan. (Marrs. Aff. ¶ 45.)

The United States' Response: The United States does not dispute Dey's SOF No. 76. Indeed, Dey reported WAC to the pricing compendia because state Medicaid programs use it as a reference. (Henderson Ex. 24, at 299:21 - 300:5.)

77. Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (Reid Decl., Ex. 5, at 137:6-17; Reid Decl., Ex. 30, at DL-0050063-30.)

The United States' Response: The United States disputes Dey's SOF No. 77. In fact, it has been Dey's practice to wait until its reported WAC prices are 40 - 50 % above market prices before it reports a lower WAC. (Henderson Ex.117) Moreover, when Dey reduced its WAC prices, it reported the WAC changes to the pricing compendia but did not change or report any change to its AWPs. (Henderson Ex. 118.)

78. For instance, after Dey launched the 25 unit package of its ipratropium bromide inhalation solution 0.02, 0.5 mg/2.5mL, (NDCs 49502068503, 49502068524) in 1997, it set the AWP for that product at $44.10 and did not change it throughout the relevant time period. (Stiroh Decl., Figure A).

The United States' Response: The United States does not dispute that Dey set the AWP for its generic drugs and thereafter did not change it -- except when it did. Dey changed its AWP when it was to its competitive advantage, but never to reflect the actual average wholesaler prices of its drugs. For example, Dey raised its reported AWP for its drug Euthyrox in order to bring its AWP spread in line with its competitors. (Henderson Ex. 34 (11/7/02 Rice Dep.), at 430:6 - 431:8.) Nineteen additional examples of Dey changing the AWPs on its products can be seen in the letter from Dey's Executive Vice President of Sales and Marketing Robert Mozak dated July

18, 2000. (Reid Decl., Ex. 25) And Dey lowered the AWP on its generic albuterol product in the third quarter of 1994. (Henderson Ex. 19 (Platt Decl., Graph A4).)

79. By 1999, the WAC that Dey reported to pricing compendia for its ipratopium was $19.10 (Stiroh Decl., Figure A).

The United States' Response: The United States does not dispute that the WACs reported to pricing compendia by Dey have not included chargebacks, discounts and rebates which have served to reduce the actual acquisition cost of the drugs for the wholesalers. (Henderson Ex. 17, at 466:13 - 468:11.)

80. By 2001, the year from which the Government used prices to calculate the spreads in its Amended Complaint, the WAC that Dey reported was $15.00. (See Reid Decl., Ex. 13, at Ex. A; Stiroh Decl., Figure A).

The United States' Response: The United States does not dispute that by 2001, Dey's reported WAC remained inflated above actual acquisition cost such that by 2001 the price to a pharmacy customer of that same drug was $8.52, creating a spread of 76 % between actual acquisition cost and the inflated WAC of $15 reported by Dey. (Reid Decl., Ex. 13, at Ex. A.)

81. Approximately 90 percent of Dey's shipments to wholesalers are invoiced at Dey's WAC. (Stiroh Decl. ¶ 8; Stiroh Decl., Ex. 5.)

The United States' Response: The United States disputes Dey's SOF No. 81. The accuracy of the information set forth therein is not possible to determine from the declaration and exhibit posited by Dey in support thereof because they are based upon hearsay evidence and evidence without specific source disclosure. The United States further notes that Dey's WACs

are not and have not been representative of actual prices paid to Dey by the wholesaler class of trade. On the contrary, the WACs reported to pricing compendia by Dey have not included chargebacks, discounts and rebates which have served to reduce the actual acquisition cost of the drugs for the wholesalers. (Henderson Ex. 17 (12/11/08 Johnston Dep.), at 466:13 - 468:11.) Moreover, the calculations performed by Dey's proposed expert and relied upon by Dey in its SOF No. 81 entirely omit the inflated WAC on Dey's albuterol reported by Dey to First DataBank on May 30, 1995, as described above. That inflated WAC was not lowered until January 1998 following service on Dey of a subpoena from the U.S. Department of Health and Human Services Office of Inspector General on or about October 6, 1997. (Henderson Ex. 119, at 786:6 - 786:11, 1021:2 - 1021:7, and Dep. Ex. 555.)

82. Dey's WACs are economically meaningful invoice prices to wholesalers. (Stiroh Decl. ¶ 6; Stiroh Decl., Exs. 5 and 6.)

The United States' Response: The United States disputes Dey's SOF No. 82. Dey's WAC's are not economically meaningful prices precisely because they are merely invoice prices that do not reflect the actual prices paid to Dey by wholesalers in that they do not deduct chargebacks, discounts and rebates which have served to reduce the actual acquisition cost of the drugs for the wholesalers. (Henderson Ex. 17, at 466:13 - 468:11.) By way of example, in one instance in 2000, Dey reclassified a customer named OptiSource from a wholesaler to a retail generic distributor class of trade at the customer's request because the customer no longer wanted to be invoiced at WAC but rather wanted to be invoiced at the actual net contracting price. (Henderson Ex. 17, at 320:19 - 322:7; Henderson Ex. 120.)

83. More than 70 percent of Dey's sales to wholesalers over the time period for which data were available were within 5 percent of WAC, after adjusting for discounts and other price adjustments offered to wholesalers. (Stiroh Decl. ¶ 10, Ex. 6.)

The United States' Response: The United States disputes Dey's SOF No. 83. The accuracy of the information set forth therein is not possible to determine from the declaration and exhibit posited by Dey in support thereof because they are based upon hearsay evidence and evidence without specific source disclosure. Dr. Stiroh has not properly disclosed the bases of her analyses, and the calculations cannot be replicated. (Henderson Ex. 19, ¶¶ 17-21.) Moreover, the calculations performed by Dey's proposed expert and relied upon by Dey in its SOF No. 83 appear entirely to omit indirect sales to wholesalers and therefore necessarily omit chargebacks paid to wholesalers involved in such indirect sales. Had chargebacks been included in the proposed expert's calculations, the spread between wholesaler costs and WAC would have been much greater because "the way the system is set up [at Dey], the WAC is specifically designed to be above the highest contract price." (Henderson Ex. 54, at 320:6 - 320:9.) Had Dr. Stiroh included all wholesaler transactions, including those sales to wholesalers for which a chargeback was ultimately processed, in order to compare the average sales prices of product sold to wholesalers as compared to the reported WACs, then, of these wholesaler transactions, only approximately 3.3% of Dey's sales to wholesalers over the time period were within 5 percent of reported WAC, at WAC or above WAC. The vast majority of the sales to wholesalers, or approximately 96.7%, were at net prices that were more than 5% below the reported WAC price. (Henderson Ex. 19 (Platt Decl.) ¶ 23.)

84. As Figure 2 and Appendix B to the Bradford Declaration illustrates, prices paid to

wholesalers by off-contract customers can be above Dey's WAC. (Bradford Decl. Figure 2; Appendix B.)

The United States' Response: The United States disputes Dey's SOF No. 84. The wholesaler data upon which Dr. Bradford relies is incomplete and unreliable. For example, the data from Cardinal Health, upon which Dr. Bradford relies, consists of the "Distrack" database produced by Cardinal pursuant to subpoena. That database lacks the "Rebate Management System" ("RMS") database that contains rebates, billbacks, and other discounts. The RMS database has never been produced to the parties. (Henderson Ex. 121, at 275:12 - 276:10.) The Cardinal 30(b)(6) representative Neil Warren testified that if one does not have the information from the Rebate Management System database and merely uses the data from the Distrack system alone, one would overstate the true net price paid by retail pharmacies, due to the failure to account for rebates, billbacks, or other items in the RMS system. (*Id*. at 278.)

85. In 1991, Congress enacted the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") which created the Medicaid rebate program which lowered each state program's Medicaid costs through rebates from drug manufacturers pursuant to contract. OBRA 90 created the Average Manufacturer Price ("AMP"). (Reid Decl., Ex. 31.)

The United States' Response: The United States does not dispute Dey's SOF No. 85, but further notes that under OBRA 90, once a manufacturer enters a contract with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. *See* 42 U.S.C. § 1396r-8(d). In addition, Congress mandated that AMP data be kept confidential.

86. Meeting minutes from a November 27-28, 1990 meeting of a State Medicaid Directors'

Association Pharmacy Reform TAG Meeting which addressed Medicaid rebates and which was co-chaired by Larry Reed, then Technical Director, Division of Pharmacy at HCFA/CMS, state that there was a "general discussion of state's need to know both AMP and best price for policy reasons (to establish a pharmacist reimbursement baseline) and to calculate rebate amounts." (See Reid Decl., Ex. 32, at AL-ARCH 0001124.)

The United States' Response: The United States does not dispute the content of the document, but disputes its materiality and any implication that it evidences a decision by HCFA that AMP information be used for purposes of reimbursement. The language selectively quoted by Dey is taken out of context and is misleading. The meeting concerning which the summary was prepared and to which Dey refers in its SOF No. 86 took place just a few weeks after passage into law of OBRA 90. The summary reviews approximately forty different topics, issues and questions discussed at a meeting of state Medicaid Directors concerning OBRA 90 and does not in any manner represent determinations by any governmental agency or representative concerning the meaning or requirements of OBRA 90. The United States further incorporates by reference paragraphs 98 - 116 of the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants ("US-C-SF").

87. Following the passage of OBRA 90, federal law required Dey to enter into a Rebate Agreement with the United States for Dey's products to be eligible for Medicaid coverage. (See 42 U.S.C.A. § 1396r-8(a)(1) (2009); Reid Decl., Ex. 33, at 615:11-18.)

The United States' Response: The United States does not dispute Dey's SOF No. 87, but the United States further notes that once a manufacturer enters a contract with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. *See* 42 U.S.C. § 1396r-8(d).

88. On February 28, 1991 Dey and the Secretary of HHS, acting through CMS, entered into a Rebate Agreement. (Reid Decl., Ex. 34.) The terms of the Rebate Agreement applied retroactively to January 1, 1991. (Reid Decl., Ex. 34, at II(d).)

The United States' Response: Undisputed.

89. The Rebate Agreement requires Dey to provide to CMS on a quarterly basis the Average Manufacturer Price ("AMP"). (Reid Decl., Ex. 34 at II(d).) The Rebate Agreement sets forth a comprehensive definition of AMP as an average of the discounted unit price of a drug:

> (a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.
>
> (Reid Decl., Ex. 34, at § I(a) (Enclosure A).) Each of the capitalized terms incorporated in the AMP definition set forth above is further defined by the Rebate Agreement. (Reid Decl., Ex. 34, at § I .)

The United States' Response: The United States does not dispute that the Medicaid Drug Rebate Agreement defines the Average Manufacturer Price as reflected in Dey's SOF No. 89, but disputes the relevance of the AMP as the United States did not sue Dey based on the

accuracy of its reported AMPs.

90. Dey has complied with its obligations and provided its AMP to CMS each quarter for each of the Generic Subject Drugs. (Marrs Aff. ¶ 43.)

The United States' Response: The United States disputes Dey's SOF No. 90 because it is irrelevant and immaterial to the issues before the Court. The United States has not sued Dey based on the accuracy of its reported AMPs. Accordingly, whether Dey complied with its AMP obligations is irrelevant to this litigation. Further, the United States does not possess adequate information or data to determine whether Dey actually complied with its AMP obligations.

91. Both former Administrators of CMS, Thomas Scully and Bruce Vladeck, stated that CMS employees could have compared Dey's AMPs to published prices for the Dey Subject Drugs to determine the difference between those prices. (Reid Decl., Ex. 33, at 617:12-619:22; Reid Decl., Ex. 35, at 464:7-465:10.)

The United States' Response: The United States does not dispute that Mr. Scully and Mr. Vladek testified that CMS employees could have theoretically compared Dey's AMPs and published prices, but disputes any suggestion that Mr. Scully and Mr. Vladek meant that CMS employees could use the AMPs for any purposes other than the Rebate Program. (*See*, *e.g.* Henderson Ex. 122, at 282:20 - 283:4; Henderson Ex. 123, at 352:14 - 353:11; Henderson Ex. 124, at 457:19 - 460:20, 464:7 - 464:19, 584:21 - 586:4; Henderson Ex. 124A, at 246:7 - 247:11; Henderson Ex. 125, at 368:14 - 369:10.) Dey's Rebate Agreement with CMS states that the AMP information submitted by manufacturers will be kept confidential. (Reid Decl., at Ex. 34.) The United States further incorporates its statements at US-C-SF ¶¶ 98-116. Accordingly, Dey's statement is immaterial.

92. For example, Mr. Scully testified as follows:

Q. Okay. So, CMS employees, to nail this down, could sit down and take a look at the AMP for Albuterol, and compare that to the AWP for Albuterol, and calculate precisely the spread between those two points; right?
MR. NEAL: I'll object to the form.
MR. RIKLIN: Objection to form.
A. I believe that's true, yes.
Q. And that data existed within CMS Medicaid during the entire time that Dey's products were reimbursed under Medicaid; right?
MR. NEAL: Objection as to form.
A. I don't know what year we started collecting AMP, but whenever they started collecting AMP, yes.
(Reid Decl., Ex. 33, at 619:4-18).

The United States' Response: See Response to No. 91 above.

93. Under the Rebate Agreement, Dey is required to pay rebates to states based on the AMP: In order for the Secretary to authorize that a State receive payments for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.
(Reid Decl., Ex. 34, at §§ II, II(a).)

The United States' Response: The United States does not dispute that the Medicaid Drug Rebate Agreement requires Dey to pay rebates and that those rebates are based, in part, on the AMPs of its drugs. The United States disputes the relevance of these aspects of the Rebate Agreement, however, since the United States has not sued based on any of the obligations therein.

94. CMS uses the AMPs it receives from Dey to calculate the Unit Rebate Amount, or URA, an NDC-specific, per-unit amount. (Reid Decl., Ex. 34, at I (dd).)

The United States' Response: See Response No. 93 above. The United States does not dispute that CMS relied upon Dey's reported AMPs to calculate the URA for Dey's drugs.

95. CMS forwards the URAs on to state Medicaid programs, who in turn multiply the URAs by the number of units dispensed to determine the final rebate amount Dey will pay. (Reid Decl., Ex. 34, at 5; Reid Decl., Ex. 36, at 303:5-12.)

The United States' Response: The United States disputes the relevance and materiality of Dey's SOF No. 95, but does not dispute that CMS provided the URAs to the state Medicaid programs and that those state Medicaid programs used the URAs to calculate the quarterly rebate amount owed by Dey for its drugs.

96. The state Medicaid programs then send Dey invoices for the rebate amounts owed. (Reid Decl., Ex. 34, at 5; Reid Decl., Ex. 36, at 303:5-12.)

The United States' Response: The United States disputes the relevance and materiality of Dey's SOF No. 96, but does not dispute that state Medicaid programs send invoices to Dey for quarterly rebates owed in connection with Dey's drugs.

97. The administrators in charge of running the Medicaid program have testified that States have had access to AMPs. (See Reid Decl., Ex. 35, at 461:12-15, 463:19-464:06; Reid Decl., Ex. 33, at 627:13-20.) Bruce Vladeck, the Administrator of HCFA from May 1993 to September 1997, testified:

Q: So as far as you know, people within HCFA shared AMP data with state

Medicaid agencies?

A: That was my understanding.

* * *

Q: So it was entirely possible -- it was entirely possible for the heads of a state Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to what they were reimbursing for those drugs. That was entirely possible. Right?

A: It's -- I don't know any reason why it wouldn't be possible.

(Reid Decl., Ex. 35, at 461:12-15, 463:19-464:06.)

The United States' Response: The United States does not dispute that Mr. Vladek gave the testimony above, but disputes the accuracy of his testimony. In fact, states were not provided with access to AMPs (Henderson Ex. 123, at 354:10 - 355:8.), and could not use AMPs to set reimbursement even if they had such access. (Henderson Ex. 122, at 281:19-22; 286:17-22.) Responding further, the United States incorporates herein its statements of undisputed fact in US-C-SF ¶¶ 98-116.

98. Thomas Scully, the Administrator of CMS from May 2001 to December 2003, testified:

Q: Did you ever tell any state that they should calculate their reimbursement methodology for Medicaid taking into account AMP data?

A: No.

Q: Why not?

A: States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.

(Reid Decl., Ex. 33, at 627:13-20.)

The United States' Response: The United States does not dispute that Mr. Scully gave this testimony, but disputes that the States could have used the AMPs in setting their drug

reimbursement rates even if they had access to that data. (Henderson Ex. 123, at 354:10 - 355:8.) Responding further, the United States incorporates herein its statements of undisputed fact in US-C-SF ¶¶ 98-116.

99. For multisource generic drugs like the Subject Drugs, the unit rebate amount is calculated as 11% of the AMP. (See 42 U.S.C.A. 1396r-8(c)(3)(A – B) (2009); Reid Decl., Ex. 34, at 3.)

The United States' Response: The United States disputes the relevance or materiality of Dey's SOF No. 99.

100. Knowing the unit rebate amount they receive, state Medicaid agencies could simply divide that amount by 11 percent to arrive at AMP. (See 42 U.S.C. 1396r-8(c)(3)(A – B) (2009).)[1]

The United States' Response: The United States disputes the relevance and materiality of Dey's SOF No. 100. Virtually all state Medicaid officials understood that the federal government treated AMPs as confidential. *See* US-C-SF ¶¶ 115. The evidence further shows that virtually all state Medicaid officials did not attempt to calculate AMPs based on URAs or otherwise use AMPs in setting reimbursement rates. (*See*, *e.g.* Henderson Ex. 126 (Arkansas), at 70 - 72; Henderson Ex. 127 (California), at 283 - 84; Henderson Ex. 128 (Georgia), at 83 - 86; Henderson Ex. 129 (Illinois), at 72 - 74; Henderson Ex. 130 (New Hampshire), at 287 - 93; Henderson Ex. 131 (New Jersey), at 77, 102-03; Henderson Ex. 132 (North Carolina), at 112-13; Henderson Ex. 133 (Vermont), at 372 -73.)

[1]Before January 1, 1994, the rebate for generic drugs was equal to 10 percent of the AMP. (See 42 U.S.C. 1396r-8(c)(3)(A-B)(2009).) Therefore, states could have determined the AMP before 1994 by dividing the unit rebate amount by 10 percent.

101. Deirdre Duzor, the CMS Director of the Pharmacy Division for the Medicaid program, testified:

> Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
>
> A: Yes. The AMPs have been fairly transparent for generic drugs.

(Reid Decl., Ex. 37, at 679:12-17.)

The United States' Response: The United States does not dispute that Ms. Duzor provided the testimony above, but disputes the materiality and relevance of the testimony, and further disputes any suggestion that States used the URA to derive the AMP. Virtually all state Medicaid officials understood that the federal government treated AMPs as confidential. The United States incorporates its statements at US-C-SF ¶ 98-116.

102. In a 2001 report, the OIG discussed the confidentiality of the AMPs as follows:

> Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not to disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.

(See Reid Decl., Ex. 38, at 22.)

The United States' Response: The United States do not dispute that the statement above was included in a 2001 OIG report titled "Cost Containment of Medicaid HIV/AIDS Drug Expenditures," (OEI-05-99-00611, July 2001), but notes that that OIG Report is the best evidence of its contents. The United States further contends that Dey's SOF No. 102 is irrelevant and immaterial to the issues before the Court.

103. Ann Maxwell, the Government's 30(b)(6) designee and a regional inspector general at the OIG, testified that this paragraph "accurately discusses the confidentiality provisions surrounding AMP." (Reid Decl., Ex. 39, at 129:1-131:3.)

The United States' Response: The United States disputes Dey's SOF No. 103 because it is irrelevant and immaterial to the issues before the Court. Ms. Maxwell testified that the paragraph quoted in Dey SOF No. 102 accurately reflected OIG's views regarding the confidentiality provisions. Maxwell was not designated to speak on behalf of the Secretary or CMS regarding the agency's interpretation of the confidentiality provision in the Medicaid Drug Rebate statute.

104. Dey's AMP reflects a discounted unit price calculated on the basis of specific government instructions. (Reid Decl., Ex. 15, at 534:4-16; Reid Decl., Ex. 5, at 168:6-169:9.)

The United States' Response: The United States disputes Dey's SOF No. 104 because it is irrelevant and immaterial to the issues before the Court. The United States has not sued Dey over whether it reported accurate AMPs for its drugs. Accordingly, whether Dey complied with its AMP obligations is irrelevant to this litigation. Further, the United States does not possess

adequate information or data to determine whether Dey's AMPs actually reflected a discounted unit price in accordance with its obligations under the Medicaid Drug Rebate Statute and Rebate Agreement.

105. As seen in Figures A through K to the Stiroh Declaration, Dey's AMP tracks slightly below Dey's published WAC for prices through 2004. See confidential Figures A-K for prices through 2007. (Stiroh Decl., Figures A-K.)

The United States' Response: The United States disputes Dey's SOF No. 105 because it is irrelevant and immaterial. Dey's AMP prices are immaterial because they were not accessed and could not be used by federal or state personnel responsible for determining reimbursement under the Medicare or Medicaid programs. Further, the United States disputes that "Dey's AMP tracks slightly below Dey's published WAC." In fact, many of the Figures referenced by Dey show significant spreads between AMP and WAC. This is most notably true with regard to the spread between AMP and the FDB WAC for NDC # 49502-0697-03 (Fig. E), 49502-0697-60 (Fig. F), and 49502-0697-33 and 49502-0697-29 (Fig. G).

106. Since 2005, every manufacturer is required to submit ASP information on a quarterly basis for each NDC covered under Medicare Part B. (Reid Decl., Ex. 40., at 2239-45.)

The United States' Response: The United States does not dispute the statement but disputes that it is relevant or material to the issues before the Court.

107. Prior to April 1, 2008, ASP was calculated by "(i) computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and (ii) dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products." (See 42 C.F.R.

§414.904 (2009); Reid Decl., Ex. 41.)

The United States' Response: The United States does not dispute that the quoted language is a correct recitation of 42 C.F.R. § 414.904(b)(2)(I) (2009), but disputes its relevance.

108. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. (Reid Decl., Ex. 42, at 3.)

The United States' Response: The United States does not dispute Dey' SOF No. 108. *See* 42 C.F.R. § 414.804(a)(2)(i) (2009).

109. Beginning in the first quarter of 2004, Dey reported its ASPs to CMS. (Marrs Aff. ¶ 44.)

The United States' Response: The United States does not dispute Dey's SOF No. 106 but disputes its relevance and materiality.

110. The Government, through the Department of Veterans Affairs and the Department of Defense, negotiates Federal Supply Schedule ("FSS") prices for federal purchases of pharmaceuticals. (Reid Decl., Ex. 43, at 8-10.)

The United States' Response: The United States does not dispute Dey's SOF No. 110, except the United States disputes the relevancy and materiality of this statement to Dey's liability under the FCA. FSS prices are not those "generally and currently paid by providers" as required under the regulations relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq., nor an Average Wholesale Price as required under the regulations and statute relating to reimbursement for Medicare, 56 Fed. Reg 59505-59524. (Nov. 25, 1991); Balanced Budget Act

of 1197, Pub. L. No. 105-33, 111 Stat.251. Comparisons between the Veterans Administration (VA) drug purchasing data and Medicare or Medicaid reimbursement are not useful because the Medicare and Medicaid programs, unlike the VA, do not purchase drugs directly from manufacturers. Rather, Medicare and Medicaid reimburse providers who purchase drugs and who lack the purchasing power of the VA. The VA purchases drugs in much larger volumes than Medicare providers and can leverage discounts directly from manufacturers. *See* US-C-SF ¶ 14.

111. The FSS contains prices at which federal buyers are able to purchase pharmaceuticals. (Reid Decl., Ex. 43, at 8-10.) FSS prices for generic drugs are negotiated based on contract price and term information for most favored customers, which is requested from and provided by drug manufacturers, such as Dey. (Reid Decl., Ex. 43, at 8-10.)

The United States' Response: The United States dos not dispute Dey's SOF No. 11, except the United States disputes the relevancy and materiality of this statement to Dey's liability under the FCA. FSS prices based on information relating to most favored customers are not those "generally and currently paid by providers" as required under the regulations and statute relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq., nor is an FSS price an Average Wholesale Price as required under regulations and the statute relating to reimbursement for Medicare, 56 Fed. Reg 59505-59524 (Nov. 25, 1991); Balanced Budget Act of 1197, Pub. L. No. 105-33, 111 Stat.251. *See* further the response to No. 110 above.

112. As stated in the VA Federal Supply Schedules: "Product and/or service pricing as well as other terms/conditions negotiated for an FSS contract are based upon an offeror's commercial practices. The negotiation process begins with an evaluation (price analysis) of an offeror's most favored commercial customer (MFC) prices and related terms and conditions." (Reid Decl., Ex. 44, at Introduction.)

The United States' Response: The United States does not dispute that Dey has correctly, but selectively, quoted from the VA Federal Supply Schedules document dated 2004; the entirety of the document referenced is the best evidence of its contents. The United States disputes the relevancy and materiality of this statement to Dey's liability under the FCA, however. FSS prices based on information relating to most favored customers are not those "generally and currently paid by providers" as required under the regulations and the statute relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq., nor an Average Wholesale Price as required under regulations relating to reimbursement for Medicare, 56 Fed. Reg 59505-59524. (Nov. 25, 1991). Balanced Budget Act of 1197, Pub. L. No. 105-33, 111 Stat.251. *See* further the response to No. 110 above.

113. Administered by VA through multiple award contracts with manufacturers, the FSS for pharmaceuticals is a list of over 17,000 brand name and generic drug products and their prices. (Reid Decl., Ex. 43, at 9, n.5.)

The United States' Response: The United States does not dispute that Dey has correctly, but selectively, quoted from a GAO report entitled "DOD and VA Pharmacy Progress and Remaining Challenges in Jointly Buying and Mailing Out Drugs". The entirety of the report referenced is the best evidence of its contents. See Response No. 110 above.

114. The FSS prices are not confidential and recent prices are reported by the US Department of Veterans Affairs on its web site. (See Reid Decl., Ex. 45.)

The United States' Response: The United States objects to the statement because it is irrelevant, particularly insofar as the statement relates to only the availability of FSS pricing

information today, not at any particular earlier periods, and the supporting document relied on by Dey is dated February 2009. Upon information and belief the Department of Veterans Affairs began publishing FSS pricing in 2000-2001, but the Department charged for access to the information until 2005. In 2005, the information became open to the public without charge.

115. FSS prices are lower than compendia-published prices. (Reid Decl., Ex. 43, at 9-10.)

The United States' Response: The United States does not dispute Dey's SOF No. 115, but disputes its relevancy and materiality. See Response No. 110 above.

116. The OIG examined FSS prices for albuterol in 1998. (Reid Decl., Ex. 46, at 7, 8.)

The United States' Response: The United States disputes that Dey has accurately paraphrased from the OIG document cited "Are Medicare Allowances for Albuterol Sulfate Reasonable;" which concluded that Medicare was paying excessive amounts for Albuterol compared to amounts paid by Medicaid and certain groups of purchasers including the VA; the entirety of the report is the best evidence of its contents. Further, the United States disputes the relevancy and materiality of this statement. See the response to No. 110 above.

117. The OIG has published ten reports studying the acquisition cost of Albuterol:

- "Medicare Payments for Nebulizer Drugs" OEI-03-94-00390 (February 1996) (Reid Decl., Ex. 47);
- "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996) (Reid Decl., Ex. 48);
- "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June

1996) (Reid Decl., Ex. 49);

- "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290 (December 1997) (Reid Decl., Ex. 50);
- "Are Medicare Allowances for Albuterol Sulfate Reasonable?" OEI-03-97-00292 (August 1998) (Reid Decl., Ex. 46);
- "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293 (November 1998) (Reid Decl., Ex. 51);
- "Medicare Reimbursement of Albuterol" OEI-03-00-00311 (June 2000) (Reid Decl., Ex. 52);
- "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001) (Reid Decl., Ex. 53);
- "Excessive Reimbursement for Albuterol" OEI-03-01-00410 (March 2002) (Reid Decl., Ex. 54); and
- "Update: Excessive Medicare Reimbursement for Albuterol" OEI-03-03-00510 (January 2004) (Reid Decl., Ex. 55.)

The United States' Response: The United States disputes the statement with regard to OEI-03-97-00290 and OEI-03-94-00390, inasmuch as those reports did not examine actual acquisition costs. For example, OIG report #OEI-03-94-00390, examined payments made by the Medicare program for three selected drugs(one of which was Albuterol Sulfate) and compared them to payments made by Medicaid (Tab 50 at p. 1); the entirety of the reports referenced is the best evidence of their contents. As a result of the instant investigation and litigation, the United States has learned that, due to the unlawful conduct of Dey and others, the amounts paid by Medicaid for Alburterol Sulfate in fact appear not to be based on "acquisition cost," but instead appear to be based, at least in part, on fraudulently reported figures and that have no meaningful relationship to actual acquisition cost. Language in the reports themselves indicates disapproval

of AWPs that exceeded providers' actual acquisition costs. See, for example, "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290, Tab 50 at ii, referring to "excessive payments" because " The published AWPs that are currently being used. . . . to determine reimbursement bear little or no resemblance to actual wholesale prices that are available." The United States further dispute the statement to the extent it implies government knowledge of actual average prices generally and currently paid in the market, inasmuch as the cited reports, insofar as they investigate actual acquisition costs of Dey products, only determined acquisition costs of a small number of transactions occurring within narrow time frame. Thus none of the reports, individually or together, could form a workable basis for setting reimbursement rates under the Medicare or Medicaid programs. To the extent certain of the reports identified in the statement consider prices paid by the VA, see Response No. 110 above.

118. In "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996), the OIG concluded that members of pharmaceutical buying groups could purchase albuterol sulfate for between 56 and 70 percent lower than the $0.43 per milliliter paid by Medicare at the time. (Reid Decl., Ex. 48, at 5-6.)

The United States' Response: The United States does not dispute that in 1996 the Office of Inspector General published a report entitled "A Comparison of Albuterol Sulfate Prices" which noted the prices five buying groups could negotiate; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1996 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy of the report to Dey's liability under the FCA, however. The report does not mention Dey. Language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs;

See, for example Tab 48 at p. 7, noting such AWPs resulted in payments for nebulizer drugs that were "inappropriately high" as " the median of the published average wholesale price does not reflect the actual wholesale price of albuterol sulfate." See further the response to No. 110 above.

119. In "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996), the OIG concluded that Medicare suppliers could acquire albuterol sulfate as low as $0.12 per milliliter, while the price paid by Medicare was $0.43 per milliliter. (Reid Decl., Ex. 49, at 6.)

The United States' Response: The United States does not dispute that in 1996 the Office of Inspector General published a report entitled "Suppliers' Acquisition Costs for Albuterol Sulfate" or that Dey has paraphrased from that report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1996 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy of the report to Dey's liability under the FCA, however. The report does not mention Dey. Language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; See, for example Tab 49 at p. 9 noting "Medicare's allowances for albuterol sulfate [based on AWP] are excessive" as HCFA had been "unsuccessful in gathering the data to determine EAC." *See* further the response to No. 110 above.

120. In December, 1997, the OIG reported that the actual average wholesale price for albuterol sulfate, J7620, in 1995 was $0.19, $0.22 lower than the $0.41 average Medicare reimbursement amount for that time. (Reid Decl., Ex. 50, at Appendix B, page B-2.)

The United States' Response: The United States disputes that Dey has accurately stated

what was reported in the 1997 Office of Inspector General report entitled "Excessive Medicare Payments for Prescription Drugs" ; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1995 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy of the report to Dey's liability under the FCA, however. The report does not mention Dey, and language in the report, including its title itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example Tab 50 at ii noting "excessive payments for prescription drugs" as the " published AWPs that are currently being used. . . for reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." *See* further the response to No. 110 above.

121. In August, 1998, the OIG reported that Medicare will pay between 56 and 550 percent more for albuterol than FSS prices available to the VA and up to 333 percent more than some pharmacies pay to acquire albuterol. (Reid Decl., Ex. 46, at 7, 8.)

The United States' Response: The United States does not dispute that in 1998 the Office of Inspector General published a report entitled "Are Medicare Allowances for Albuterol Sulfate Reasonable" or that Dey has paraphrased from that report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy and materiality of this statement to Dey's liability under the FCA, however. The report does not mention Dey, and language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example Tab 46 at p. iv, 6 noting Medicare is making "excessive payments for albuterol sulfate" compared to "actual prices in the

marketplace." *See* further the response to No. 110 and 117 above.

122. In November, 1998, the OIG reported that the median price for the Department of Veterans Affairs (the "VA") to purchase albuterol sulfate unit dose was $0.12, while Medicare's median allowable price was $0.47, resulting in a 292 percent spread. (Reid Decl., Ex. 51, at Appendix B, page B-1.)

The United States' Response: The United States does not dispute that in 1998 the Office of Inspector General published a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" or that Dey has paraphrased from that report. The United States disputes that the report mentions "spreads" ; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy and materiality of this statement to Dey's liability under the FCA, however. VA FSS prices are not those "generally and currently paid by providers" as required under the regulations relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq., nor are the an Average Wholesale Price as required under regulation and statute relating to reimbursement for Medicare, 56 Fed. Reg 59505-59524. (Nov. 25, 1991) ; Balanced Budget Act of 1197, Pub. L. No. 105-33, 111 Stat.251. The report does not mention Dey, and language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example Tab 51 at p. ii "actual wholesale prices available to physicians and suppliers are often significantly lower than Medicare allowed amounts" and "published AWPs . . . can be many times greater than actual acquisition costs available in the marketplace." *See* further the response to Nos. 110 and 117 above.

123. The OIG has also produced invoices for Dey's albuterol. During discovery, the Government produced working files for these reports, indicating that they bore the Bates prefixes HHD005 through HHD0014. (See Reid Decl., Ex. 56.)

The United States' Response: The United States does not dispute Dey's SOF No. 123.

124. For example, an internal OIG memorandum dated November 8, 1995 from "Karen" to "Rob," "Bob," and "Amy," discusses invoices the government received from Medicare suppliers for Dey's albuterol sulfate 0.083%. The memorandum annexes invoice prices for Dey's albuterol unit dose. (Reid Decl., Ex. 57.)

The United States' Response: The United States does not dispute Dey's SOF No. 124.

125. The memorandum notes that the lowest price suppliers pay to Dey for albuterol sulfate is $0.1167 per milliliter, and the highest price paid by suppliers for Dey's albuterol sulfate was $0.1667 per milliliter. (Reid Decl., Ex. 57, at HHD011-0915-16.)

The United States' Response: The United States disputes Dey's SOF No. 125 because it mischaracterizes the memorandum to which it refers in support of its representation of the lowest and highest prices paid by suppliers for Dey's albuterol. The memorandum does not purport to list the highest and lowest prices paid by suppliers in the marketplace.

126. The various tables annexed to the memorandum list prices for Dey's albuterol from manufacturers, suppliers, and wholesalers. (Reid Decl., Ex. 57.)

The United States' Response: The United States does not dispute Dey's SOF No. 126.

127. The Government has also specifically studied the actual acquisition cost of another of the Subject Drugs, ipratropium bromide, beginning at least as early as 1998, and the working files from the OIG indicate that the OIG also reviewed various prices for Dey's ipratropium. (See, e.g., Reid Decl., Ex. 51.)

The United States' Response: The United States does not dispute Dey's SOF No. 127.

128. In "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293, the OIG found that the VA's median price for ipratropium bromide was $1.31 per mg, while Medicare's median allowable price was $3.34 per mg, resulting in a 155% difference. (Reid Decl., Ex. 51, at Appendix B, page B-1.)

The United States' Response: The United States does not dispute that in 1998 the Office of Inspector General published a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" or that Dey has paraphrased from that report. The United States disputes that the report mentions "spreads" ; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy and materiality of this statement to Dey's liability under the FCA, however. VA FSS prices are not those "generally and currently paid by providers" as required under the regulations relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq., nor an Average Wholesale Price as required under regulation and statute relating to reimbursement for Medicare, 56 Fed. Reg 59505-59524. (Nov. 25, 1991) ; Balanced Budget Act of 1197, Pub. L. No. 105-33, 111 Stat.251. Comparisons between the Veterans Administration (VA) drug purchasing data and Medicare or Medicaid reimbursement are not useful because the Medicare and Medicaid programs, unlike the VA, do not purchase drugs directly from manufacturers. Rather, Medicare and Medicaid reimburse providers who purchase drugs directly from manufacturers. Rather, Medicare and Medicaid reimburse providers who purchase drugs and who lack the purchasing power of the VA. The VA purchases drugs in much larger volumes than Medicare providers and

can leverage discounts directly from manufacturers. *See* US-C-SF ¶ 14.

The report does not mention Dey. Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; see, for example, Tab 51 at p. ii ("actual wholesale prices available to physicians and suppliers are often significantly lower than Medicare allowed amounts" and "published AWPs . . . can be many times greater than actual acquisition costs available in the marketplace.").

129. A document produced from the OIG's working files, dated May 21, 1998, lists Federal Supply Schedule prices for several drugs, including Dey's albuterol sulfate and ipratropium bromide products. That document lists a Federal Supply Schedule price for Dey's ipratropium bromide 0.02% inhalation solution (NDC 49502-0685-60) of $40. (Reid Decl., Ex. 58.)

The United States' Response: The United States does not dispute Dey's SOF No. 129.

130. Another document bearing the same Bates prefix and dated January 1998 appears to be a print-out of various AWP prices for ipratropium from Red Book. (Reid Decl., Ex. 59.)

The United States' Response: The United States does not dispute Dey's SOF No. 130.

131. In 2001, 2002 and again in 2004, the OIG continued to find and to report that there were large spreads for ipratropium:

- In "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001), the OIG found that a median VA price was $0.84 per milligram, whereas the median Medicare allowable amount was $3.34, creating a spread of 297 percent. The report also found that the median catalog price for ipratropium was $1.53, creating a spread of 118 percent. (Reid Decl., Ex. 53, at Appendix D, page 16-17.)

- In "Excessive Medicare Reimbursement for Ipratropium Bromide" OEI-03-01-00411 (March 2002), the OIG reported that the median Medicare allowable cost for ipratropium bromide was $3.34, while the median VA price for ipratropium bromide was $0.66, resulting in a "spread" of 406 percent. The report also

contained a chart, tracking the Medicare allowable amount against the VA prices between 1998 and 2001. The report also found that the median price for ipratropium appearing in wholesale catalogs was $0.82 per milligram, creating a spread of 307 percent between the catalog price and the Medicare allowable amount. (Reid Decl., Ex. 60, at 9-11.)

- In "Update: Excessive Medicare Reimbursement for Ipratropium Bromide" OIG-03-03-00520 (January 2004), the OIG found that Medicaid set a FUL for ipratropium bromide at $1.17 per mg, 65% less than the $3.34 that Medicare pays for the same drug. The median wholesaler price for that same drug is $0.57, and the median GPO price is $0.62. (Reid Decl., Ex. 61, at ii.)

The United States' Response: The United States does not dispute that in 2001, 2002 and 2004 the Office of Inspector General published the reports stated or that Dey has paraphrased from those reports except the United States disputes that the report mentions "spreads" ; the entirety of the reports referenced is the best evidence of their contents. The United States does not dispute that in 2001, 2002 and 2003 pharmacies could buy drugs at discounts from AWP. The United States does dispute the relevancy and materiality of this statement to Dey's liability under the FCA, however. The reports do not mention Dey. Finally, language in the reports themselves indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example, Tab 61 at p. iv " This report is part of a series of reports on ipratropium bromide that have consistently found that the published average wholesale prices . . . bear little or no resemblance to actual wholesale prices" resulting in the medicare program losing "progressively more money every year" and paying "excessive reimbursements" Tab 60 at iii. The United States further disputes the statement to the extent it implies government knowledge of actual average prices generally and currently paid in the market, inasmuch as the cited reports, insofar as they investigate actual acquisition costs of Dey products, only determined acquisition costs of a small number of transactions occurring within narrow time frame. Thus none of the

reports, individually or together, could form a workable basis for setting reimbursement rates under the Medicare or Medicaid programs. To the extent certain of the reports identified in the statement consider prices paid by the VA, see Response No. 110 above.

132. The OIG working files also contain pricing information for Dey's cromolyn sodium. For example, a February, 1996 fax from Dr. Robert Zone of Palmetto to Robert Vito at the OIG contained a contract showing the 1994 price of Dey's cromolyn to be $60 per package. (Reid Decl., Ex. 62.)

The United States' Response: The United States does not dispute Dey's SOF No. 132.

133. Mary Riordan, counsel to the OIG, produced copies of a Pharmaceutical Buyers, Inc. catalog dated November 28, 1995, which listed contract prices for Dey's cromolyn at $28.00 per package. (Reid Decl., Ex. 63, at HHD194-1165.)

The United States' Response: The United States does not dispute Dey's SOF No. 133.

134. Ms. Riordan also produced a contract between Dey and Gerimed, a provider group purchasing organization, with an effective date of August 1, 1996, listing contract prices for its cromolyn at $25.00 and $49.00 per package. (Reid Decl., Ex. 64.)

The United States' Response: The United States does not dispute Dey's SOF No. 134.

135. The OIG also obtained invoices from 1999 from pharmacies for Dey's albuterol (NDC 49502-0689-02) in connection with its reviews of pharmacy acquisition costs in states such as West Virginia and Indiana. (Reid Decl., Ex. 65, at HHD027-0342; Reid Decl., Ex. 66, at HHD028-0207.)

The United States' Response: The United States does not dispute Dey's SOF No. 135.

136. In addition to the information it gathered through its own investigations, the Government requested and began receiving contract prices for inhalation drugs, including the Subject Drugs, from the relator in this case, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-

Care"). (Reid Decl., Ex. 67, at 860:14-863:1; 874:9-875:10; 876:8-20; Reid Decl., Ex. 68.) Ven-A-Care obtained the pricing information for Dey's drugs from wholesalers and group purchasing organizations ("GPO"). (Reid Decl., Ex. 67, at 786:11-788:13.)

The United States' Response: The United States disputes Dey's SOF No. 136 because the cited testimony and document do not support or even mention information gathered by the Government through its own investigation. The information contained in the evidence cited relates to information provided to the Office of Evaluations and Inspections (OEI) at OIG and not its Office of Investigations, and the information was provided in connection to a report being prepared within OEI. (Henderson Ex. 134 (12/8/08 Jones Dep.), at 860:14 - 861:13; Henderson Ex. 135 (2/5/08 Vito Dep.), at 765:15 - 765:19.) Moreover, Ven-A-Care began to provide information to OIG regarding pharmaceutical pricing issues in 1994 and first provided information to OIG regarding inhalant drugs in 1995. Also, Ven-A-Care's pricing information for Dey's drugs came from sources including its own pricing records, GPO's, traditional wholesalers and special wholesalers.

137. For instance, a fax sent by Ven-A-Care to the OIG on March 19, 1996 contains both Dey's contract prices to a GPO as well as the AWPs for Dey's drugs. (Reid Decl., Ex. 68.) Robert Vito at the OIG requested this information to assist in the preparation of the OIG reports relating to albuterol pricing. (Reid Decl., Ex. 67, at 861:6-862:20.) The contract price for Dey's albuterol unit dose was $.13 per milliliter while at the same time the AWP was $.40 per milliliter, three times that of the contract price. (Reid Decl., Ex. 68, at 2, 3.) Dey's contract price for metered dose inhalers was $13.50 while AWP was $21.70. (Reid Decl., Ex. 68, at 2, 3.) The contract price for Dey's cromolyn was $.23 per milliliter while the AWP was $.35 per milliliter, more than one and a half times greater than the contract price. (Reid Decl., Ex. 68, at 2, 3.)

The United States' Response: The United States does not dispute Dey's SOF No. 137 except that the testimony cited does not support the statement that Robert Vito requested the information to assist in more than one OIG report.

138. Throughout the relevant time period, Ven-A-Care continued to send the OIG wholesaler price information and GPO contract information for the Subject Drugs. (Reid Decl., Ex. 70; Reid Decl., Ex. 71; Reid Decl., Ex. 72; Reid Decl., Ex. 73; Reid Decl., Ex. 74; Reid Decl., Ex. 75; Reid Decl., Ex. 76.)

The United States' Response: The United States does not dispute Dey's SOF No. 138 but notes further that Ven-A-Care also provided OIG with, *inter alia*, information regarding its own experiences as a pharmacy and participant in the pharmaceutical marketplace, together with its understanding of the marketplace.

139. As early as 1998, Ven-A-Care provided the OIG passwords to online electronic databases of wholesalers and GPOs, allowing the federal government access to all prices sold by various wholesalers and GPOs. (Reid Decl., Ex. 77, at 1094:9-21; 1095:15-22.) In January 2001, Ven-A-Care gave the federal government a laptop containing the Econolink database. (Reid Decl., Ex. 78, at 13:8-15; 18:23-20:10.) The laptop from Ven-A-Care gave the federal government a working database that gave them all the pricing information Ven-A-Care possessed. (Reid Decl., Ex. 78, at 76:20-77:20; 81:12-20.)

The United States' Response: The United States does not dispute this paragraph except to state that the passwords to databases gave the federal government access only to the pricing information contained in the databases unlocked with the passwords, available to Ven-A-Care, and the testimony cited by Dey suggests nothing further in this regard. (Henderson Ex. 136 (12/9/08 Jones Dep.), at 1095:15 - 1095:22.) Additionally, the laptop from Ven-A-Care gave the federal government a working database that gave them all the pricing information in that database that Ven-A-Care possessed.

140. Ven-A-Care also forwarded to the federal government several sales circulars and advertisements showing that rebates were available for Dey's products. (Reid Decl., Ex. 67, at 926:9-13; see also Reid Decl., Ex. 71, at VAC MDL43586; Reid Decl., Ex. 67, at

883:6-9; Reid Decl., Ex. 79; Reid Decl., Ex. 67, at 925:1-9; Reid Decl., Ex. 80; Reid Decl., Ex. 67, at 927:17-21; Reid Decl., Ex. 81; Reid Decl., Ex. 67, at 955: 13-21; Reid Decl., Ex. 82; Reid Decl., Ex. 67, at 969:10-13.)

The United States' Response: The United States does not dispute Dey's SOF No. 140.

141. On March 19, 1998, Ven-A-Care made a presentation before the National Association of Medicaid Fraud Control Units (NAMFCU). (Reid Decl., Ex. 407:17-408:22.) Sign-in sheets demonstrate that representatives from every state except Alabama received the materials from this meeting. (Reid Decl., Ex. 84; Reid Decl., Ex. 85; Reid Decl., Ex. 86; Reid Decl., Ex. 67, at 1014:4-1016:18.) Around the same time, Ven-A-Care made a similar presentation to officials at CMS. (Reid Decl., Ex. 407:17-408:22.) Ven-A-Care made a similar presentation to CMS in 1995. (Reid Decl., Ex. 67, at 835:14-841:22.) At these presentations, Ven-A-Care contended that AWPs and WACs exceeded the actual acquisition costs of Medicare and Medicaid providers, that there were mega-spreads between AWP and actual acquisition costs, and that drug manufacturers marketed the spread to gain market share. (Reid Decl., Ex. 77, at 1119:21-1120:16.)

The United States' Response: The United States disputes Dey's SOF No. 141 in part because it twice cites to Reid Decl. Ex. 407 as support for the statements therein, but the exhibits attached to the Reid Declaration only go up to Exhibit 296, thereby depriving the United States and the Court of an opportunity to examine the evidence upon which Dey relies. Additionally, Dey is incorrect in saying that representatives from every state except Alabama received the materials at the NMFCU meeting of March 19, 1998. As is evident from the evidence submitted by Dey, Idaho did not receive such materials either. On the occasions referenced in Dey's SOF No. 141, the federal agency was known as HCFA, not CMS. The final sentence of Dey's SOF No. 141 is incorrect in two respects. First, the testimony cited does not support the statement that that Ven-A-Care made such contentions at meetings with HCFA/CMS. Second, the testimony cited does not support the statement or suggestion that Ven-A-Care used the term "mega-spreads" during any of its presentations.

142. Ven-A-Care filed a sealed qui tam FCA action against Dey on August 13, 1997, seeking to recover damages on behalf of both the Medicare and Medicaid programs arising from Dey's albuterol sulfate unit dose and cromolyn sodium. (Reid Decl., Ex. 94, at ¶¶ 120-121.) Pursuant to the procedural requirements of the FCA, Ven-A-Care was required to disclose this qui tam complaint and all the material evidence in within its possession to the federal government prior to the filing of the complaint. (See 31 U.S.C.A. § 3730(b)(2) (2009).) On December 9, 1999, Ven-A-Care filed an amended qui tam complaint which included allegations concerning Dey's ipratropium bromide. (Reid Decl., Ex. 94, at ¶¶ 141-142.)

The United States' Response: The United States disputes Dey's SOF No. 142 because it states that Ven-A-Care filed its FCA action against Dey on August 13, 1997. As plainly evidenced from the evidence cited in support of that statement, the document filed by Ven-A-Care on August 13, 1997, amended a complaint filed on June 23, 1995. It is not disputed that Ven-A-Care subsequently filed an amended qui tam complaint which included allegations concerning Dey's ipratropium. bromide. Additionally, Dey misstates the legal requirements set forth in the Federal False Claims Act. The FCA required Ven-A-Care to serve the Government with a copy of the complaint, and written disclosure of "substantially all material evidence and information the person possesses." Moreover, the FCA does not require that the complaint and written disclosure be served before the filing of the complaint. *See* 31 U.S.C.A. § 3730(b)(2) (2009).

143. The Government did not intervene within the original 60 day seal period provided by the FCA following the filing of these complaints and instead sought and obtained extensions of the seal period for nine years. See In re Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 389, 392 (D. Mass. 2007). During the nine year seal period, the Government subpoenaed documents from Dey and other drug manufacturers (Reid Decl. Ex. 96, at ABT008-0340); created an electronic database for the storage and review of those documents (Reid Decl. Ex. 97, at ABT008-1069); coordinated discovery efforts with state Medicaid Fraud Control Units (Id.); interviewed witnesses (Reid Decl. Ex. 98,

at ABT008-1040); retained an expert to assist with damages calculations (Reid Decl. Ex. 99, at 2); and developed a computer model to assess damages (Reid Decl. Ex. 100, at 5).

The United States' Response: The United States does not dispute Dey's SOF No. 143 but notes that, as evidenced by the documents upon which Dey relies in support of its statement, Dey became aware of the *qui tam* law suit filed by Ven-A-Care within just two months of August 13, 1997. Indeed, the October 1997 unopposed motion for extension of the seal, a redacted copy of which is attached to the Reid Declaration as Exhibit 96, expressly states that each of the defendants had been served with subpoenas for the production of documents and references the earlier order of the court granting a partial lifting of the seal as to the named defendants. (Reid Decl. Ex. 96, at ABT008-0340.) Despite such knowledge of the lawsuit and the government investigation concerning its reported prices, Dey's executives engaged in a prolonged campaign of deception evidenced in part, but by no means exclusively, by their repeated denials under oath that Dey created or marketed the spread between its reported AWPs and WACs and the prices at which their albuterol, cromolyn sodium and ipatropium bromide products were currently and generally available in the marketplace. In this regard, the United States incorporates by reference its response to Dey's SOF No. 145 below and the US-D-SF ¶¶159-175 as if more fully set forth herein at length.

144. The OIG issued a first subpoena to Dey on or about October 31, 1997 and a second subpoena on or about July 27, 2000. (Marrs Aff. ¶ 49.)

The United States' Response: The United States does not dispute Dey's SOF No. 144. Indeed, Dey's CEO Charles Rice has admitted that Dey has been aware since 1997 that an issue exists with respect to Dey's reporting of prices to government authorities. (Henderson Ex. 83, at

113:18 - 114:2.)

145. Over an eight year period from October 1997 to September 2005, Dey produced or made available for inspection approximately a combined 2.3 million pages of documents on at least eight separate occasions to the HHS-OIG (most of which were also produced to Ven-A-Care in connection with the Texas and/or Florida pricing litigations). (Marrs Aff. ¶ 50.)

The United States' Response: The United States disputes Dey's SOF No. 145 insofar as it suggests forthrightness on the part of Dey in the face of government investigations and compulsory subpoenas. In fact, Dey engaged in a deliberate strategy of hiding from the government evidence of its unlawful conduct, including its program of enlisting its sales force in marketing the spread on its generic products. See US-D-SOF ¶¶ 159-175, which describe Dey's false denial of marketing the spread, Mr. Mozak's instruction to shred documents, and Deys' belated disclosure of critical documents evidencing Dey's motive in reporting false prices and its company policy of promoting the spread on its products.

146. As of December, 1997, Dey had produced 2,697 pages of documents in response to the OIG subpoena, which included various contract awards listing contract prices and other pricing information for many of the Subject Drugs. (Marrs Aff. ¶ 51.)

The United States' Response: The United States disputes Dey's SOF No. 146 because it mischaracterizes the evidence cited in support thereof. In her affidavit, Ms. Marrs does not indicate that the referenced 2697 pages were produced in response to an OIG subpoena. The United States further disputes Dey's SOF No. 146 insofar as it suggests forthrightness on the part of Dey in the face of government investigations and compulsory subpoenas. The United States incorporate herein by reference its response to Dey's SOF No. 145 in its entirety.

147. For example, Dey produced wholesale price lists, contract modifications, contract awards, and contract proposals for the Subject Drugs for customers such as Greater New York Hospital Association, Community Pharmacy Network, and Pharmaceutical Buyers, Inc. (Reid Decl., Ex. 101; Reid Decl., Ex. 102; Reid Decl., Ex. 103; Reid Decl., Ex. 104; Reid Decl., Ex. 105; Reid Decl., Ex. 106; Reid Decl., Ex. 107; Reid Decl., Ex. 108.)

The United States' Response: The United States disputes Dey's SOF No. 147 insofar as it suggests forthrightness on the part of Dey in the face of government investigations and compulsory subpoenas. The United States incorporates herein by reference its response to Dey's SOF No. 145 in its entirety.

148. Since January 1999, Dey sent letters to state Medicaid administrators in which Dey explicitly described the nature of its published AWPs and WACs when new products were introduced or when prices were changed. (Reid Decl., Ex. 30; Reid Decl., Ex. 109; Reid Decl., Ex. 110; Reid Decl., Ex. 111; Reid Decl., Ex. 112; Reid Decl., Ex. 113; Reid Decl., Ex. 114; Reid Decl., Ex. 115; Reid Decl., Ex. 116; Reid Decl., Ex. 117; Reid Decl., Ex. 118; Reid Decl., Ex. 119; Reid Decl., Ex. 120.)

The United States' Response: The United States disputes Dey's SOF No. 148 because it is irrelevant and immaterial to the issues before the Court and not supported by admissible evidence. The evidence that it relies upon consists of a series of 14 letters but Dey submits no evidence that these letters were sent. Moreover, contrary to Dey's assertions, the letters do not explicitly or even accurately describe the nature of Dey's published AWPs and WACs when new prices were introduced or when prices were changed. Nine of the 14 letters state: "It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators." (Reid Decl., Ex. 109, 110, 111, 113, 114, 115, 117, 118.) Yet this could not have been consistent with industry practice or understood by state and federal Medicaid

regulators because it is not true. In fact, Dey changed its AWP when it was to its competitive advantage, but never to reflect the actual average wholesaler prices of its drugs.

For example, Dey raised its reported AWP for its drug Euthyrox in order to bring its AWP spread in line with its competitors. (Henderson Ex. 34, at 430:6 - 431:8). Nineteen additional examples of Dey changing the AWPs on its products can be seen in the letter from Dey's Executive Vice President of Sales and Marketing Robert Mozak dated July 18, 2000, a copy of which is marked as Exhibit 25 to the Declaration of Sarah Reid, DL-0050108, submitted by Dey in support of its motion. And Dey lowered the AWP on its generic albuterol product in the third quarter of 1994. (Henderson Ex. 19, Graphs A4, A6.) Even two of the letters submitted by Dey in support of its SOF No. 148 directly contradict this statement set forth in nine of the others by baldly stating: "DEY has chosen to change the AWP on these products at this time principally due to current conditions in the marketplace." (Reid Decl., Ex. 116, 120.)

Moreover, each of these letters, presenting misrepresentations of fact to federal and state Medicaid regulators, fail to provide the government agencies to which they are addressed any information concerning actual average wholesaler prices or wholesaler acquisition costs for any of its drugs. In this regard, Dey's Senior Manager of Contracts Russell Johnston, who had the responsibility of reporting Dey's AWPs and WACs, testified concerning these letters to Medicaid Administrators as follows:

> Q. Okay. In coming back to the language in Exhibit 53, has Dey ever to your knowledge made an attempt to -- any attempt to determine the average price at which its -- or to estimate the average price at which its products are sold by wholesalers?
> MR. DOYLE: Objection as to form.
> A. And again, I'm trying to understand your question. I don't know of any way Dey has any visibility to what the wholesaler actually sells the product for.

Q. So to your knowledge Dey has never made any attempt to inform states of what the actual wholesale prices are for its products?
MR. DOYLE: Objection as to form.
Q. Is that fair to say?
MR. DOYLE: Objection as to form.
A. And again, we report Dey's published wholesale acquisition cost and average wholesale price.
Q. And to your knowledge has Dey ever made any effort to inform states of what the actual average of the wholesale prices are for Dey's drugs?
MR. DOYLE: Objection as to form.
A. And not only -- I don't understand what that term would mean and I don't know one way or another if Dey has.
Q. Is that because you don't understand what average wholesale price means?
MR. DOYLE: Objection as to form.
A. You didn't -- you talked about an estimate of something and I don't know what that estimate would be.

(Henderson Ex. 17, at 462:13 - 464:3. See also Henderson Ex. 137, consisting of an August 10, 1999, memorandum to Dey employee Russell Johnston providing two different forms of letters to be sent to Medicaid Administrators, one containing Dey's reported AWPs and WACs to be sent to states whose Medicaid agency bases reimbursement on WAC, and another containing just Dey's reported AWPs to be sent to states whose Medicaid agencies reimburse based upon AWP.

149. Dey has also sent letters with similar language to Medicare Durable Medical Equipment Regional Carriers ("DMERCs"). (Reid Decl., Ex. 111, at DEYLABS0415397.)

The United States' Response: The United States disputes Dey's SOF No. 149 and in doing so The United States incorporates herein by reference their response to Dey's SOF No. 148 in its entirety as if fully set forth.

150. Multiple states have produced similar letters which they received from Dey, such as Alabama, Connecticut, Illinois, Maryland, Texas, Virginia, and Wisconsin. (Alabama: Reid Decl., Ex. 121; Connecticut: Reid Decl., Ex. 122; Illinois: Reid Decl., Ex. 123; Maryland: Reid Decl., Ex. 124; Texas: Reid Decl., Ex. 125; Reid Decl., Ex. 126; Reid Decl., Ex. 127; Reid Decl., Ex. 128; Virginia: Reid Decl., Ex. 129; Wisconsin: Reid Decl., Ex. 130; Reid Decl., Ex. 131; Reid Decl., Ex. 132; Reid Decl., Ex. 133; Reid Decl., Ex. 134; Reid Decl., Ex. 135; Reid Decl., Ex. 136; Reid Decl., Ex. 137.)

The United States' Response: The United States disputes Dey's SOF No. 150 because it is irrelevant and immaterial to the issues before the Court. The letters to state Medicaid programs that Dey relies on to show government knowledge of Dey's conduct did not disclose Dey's truthful AWPs or WACs to the programs, and thus could not be used by states to change the reimbursement for Dey's drugs. (Henderson Ex. 17, at 462:13 - 464:3; Henderson Ex. 108, at 166:17 - 170:11; Henderson Ex. 138, at 480:18- 481:12; Henderson Ex. 139, at 264:18 -- 267: 6; Henderson Ex. 140, at 444:6 - 448:10; Henderson Ex. 129, at 320:9- 20; Henderson Ex. 133, at 321:5-15; Henderson Ex. 132, at 335: 20-22 - 337:1; 338:5-14.) For example, Delaware's 30(b)(6) designee, was not positive she had received the letter shown her by Dey's counsel, but her testimony established that whether she received it or not was of no moment:

> Q. After reading this, do you understand why Dey is changing the AWP -- the prices that are the subject of this letter?
> A. No.
> Q. Without knowing the actual prices for the products listed in Dey Exhibit 616, is the information in this letter useful to the Delaware Pharmacy Benefits Program?
> MR. CYR: Objection.
> MS. RAMSEY: Objection.
> THE WITNESS: No, it's not useful.
> BY MS. HEALY SMITH:
> Q. Could you make changes to the reimbursement methodology based on the information in this letter?
> A. No.

Q. Is there anything you could do with the information in this letter?
MS. RAMSEY: Objection.
MR. CYR: Objection.
THE WITNESS: Not with the information.

(Henderson Ex 138.)

Moreover, Dey provides no evidence that such letters were received by any states other than the seven states listed in Dey's statement. Seven of the letters presented by Dey in support of its SOF No. 150 state: "It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators." (Reid Decl., Ex. 125, 126, 128, 130, 131, 134, 135) Yet this could not have been consistent with industry practice or understood by state and federal Medicaid regulators because it is not true. In fact, Dey changed its AWP when it was to its competitive advantage, but never to reflect the actual average wholesaler prices of its drugs. In this regard, the United States incorporates herein by reference their response to Dey's SOF No. 148 in its entirety as if fully set forth.

151. For example, in one such letter dated August 1999, Robert Mozak, Dey's Executive Vice President for Sales and Marketing, wrote to state Medicaid administrators as well as regional Medicare benefits administrators, apprising them of a new NDC number for Dey's Albuterol Sulfate Inhalation Solution 0.5%. (Reid Decl., Ex. 111.)

The United States' Response: The United States disputes Dey's SOF No. 151 because it is irrelevant and immaterial to the issues before the Court.

152. The letter describes Dey's WAC as follows:

As you know, WAC is referred to by data reporting services and government agencies as

> an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees, and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid. (Reid Decl., Ex. 111 (emphasis in the original).)

The United States' Response: The United States disputes Dey's SOF No. 152 because it is irrelevant and immaterial to the issues before the Court. See Response to Nos. 148 and 150 above.

153. The letter goes on to describe AWP as follows:

> Further, as you also know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators. (Reid Decl., Ex. 111 (emphasis in the original).)

The United States' Response: The United States does not dispute the content of the letter but disputes the relevance and materiality of Dey's SOF No. 153. See Responses to Nos. 148 and 150 above.

154. The letter closes with the following sentence: "If you need additional information, please feel free to contact Todd Galles, Senior Product Manager, at 800-755-5560, ext. 7450." (Reid Decl., Ex. 111.)

The United States' Response: See Response No. 155 above.

155. Todd Galles, the Dey contact person listed on the August 1999 letter discussed above,

testified that he had never been contacted by anyone regarding the letter. (Reid Decl., Ex. 138, at 410:1-411:15.)

The United States' Response: The United States does not dispute that Mr. Galles testified as indicated, but disputes that the evidence is relevant or material. The letters to state Medicaid programs that Dey relies on to show government knowledge of Dey's conduct did not disclose Dey's truthful AWPs or WACs to the programs, and thus could not be used by states to change the reimbursement for Dey's drugs. See Responses to Nos. 148 and 150 above.

156. State Medicaid officials who recalled receiving such letters from Dey testified that they never contacted anyone from Dey about the statements made in the letters. (Alabama: Reid Decl., Ex. 139, at 278:4-279:21, 280:4-281:20; Arkansas: Reid Decl., Ex. 140, at 537:14-539:5; California: Reid Decl., Ex. 141, at 267:13-19; Delaware: Reid Decl., Ex. 142, at 218:4-219:21; Reid Decl., Ex. 143, at 489:1-490:14; Michigan: Reid Decl., Ex. 144, at 245:12-13, 245:17-246:20; Nebraska: Reid Decl., Ex. 145, at 264:18-265:3, 265:11-266:11; North Carolina: Reid Decl., Ex. 146, at 337:3-339:18; Oregon: Reid Decl., Ex. 147, at 169:4-170:5; Tennessee: Reid Decl., Ex. 148, at 305:18-306:17; Vermont: Reid Decl., Ex. 149, at 319:18-321:15; Virginia: Reid Decl., Ex. 150, at 301:4-15; Wisconsin: Reid Decl., Ex. 151, at 150:21-151:7, 153:11-17, 155:15-22, 157:8-18, 159:15-160:6.)

The United States' Response: The United States disputes Dey's SOF No. 156 because the testimony cited by Dey from Arkansas, California, Michigan, North Carolina, Oregon, Tennessee, Vermont, Virginia and Wisconsin contains no evidence that Dey's letters were read by anyone at the deponents' agencies. Moreover, Dey has ignored testimony by state agencies that directly contradict its SOF No. 156 and prove it to be false. By way of example, the deponent from the Alaska Medicaid program recalled both receiving Dey's letters and contacting Dey to ask it about the new AWPs that Dey had sent. (Henderson Ex. 141, at 357:1 - 358:1.) In fact, the letters to state Medicaid programs that Dey relies on to show government knowledge of Dey's conduct did not disclose Dey's truthful AWPs or WACs to the programs, and thus could

not be used by States to change the reimbursement for Dey's drugs. (Henderson Ex.17 (Johnston), at 462:13 - 464:3; Ex. 108 (Oregon), at 166:17 - 170:11; Ex. 138 (Delaware), at 480:18 - 481-12; Ex. 139 (Maryland), at 264:18 - 267; Ex. 140 (Wyoming), at 446:6 - 448:10; Ex. 129 (Illinois), at 320:9 - 320:20; Ex. 133 (Vermont), at 321:5 - 321:15; Ex. 132 (North Carolina), at 335:20 - 337:1, 338:5-14.)

157. State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (See Reid Decl., Ex. 144, at 245:12-13; 245:17-246:20.) Accordingly, Dey had no reason to believe there was any doubt that Medicaid and Medicare officials knew WAC represented the undiscounted list price used on invoices to wholesalers and its AWP was not changed over time and was not a price which would be charged or paid. See, e.g., letter from Robert Mozak to Martha McNeill at the Texas Department of Health that Dey expected that its "explanatory language" that WAC excluded discounts would come as "no surprise" to the agency. (Reid Decl., Ex. 152.)

The United States' Response: The United States disputes Dey's SOF No. 157 because it is irrelevant and immaterial, and, in addition, it mischaracterizes the testimony of Sandra Kramer cited by Dey in support of SOF No. 157. Ms. Kramer did not testify that she or any other Medicaid officials were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. Rather, in the portion of her deposition cited by Dey, Ms. Kramer responded to hypothetical questions about what she might have done had she received such a letter from Dey. She further testified that she never spoke to Ms. Ferrot from Dey, but neither says she did not speak to anyone else at Dey nor says that she is unaware of any contact initiated by her agency to Dey after Dey sent such letters. Dey cites no other testimony in support of its proposition. Indeed, contrary to Dey's further assertion that "Dey had no reason to believe that there was any doubt that Medicaid and Medicare officials knew" that what Dey said in its letters was true, Dey

had every reason to believe there was such doubt. As Dey readily admits in its SOF No. 157, many of its letters asserted that "its AWP was not changed over time." Yet in the 18 letters cited by Dey in its SOF No. 150, there are no less than 50 changes to Dey's AWPs. With such a blatant and repeated misrepresentation to Medicare and Medicaid officials, Dey had every reason to believe that anything it said would be given scant review or consideration by officials whose regular practice it was to review prices reported by First DataBank in determining reimbursement payments to pharmaceutical providers.

Moreover, the letters to state Medicaid programs that Dey relies on to show government knowledge of Dey's conduct did not disclose Dey's truthful AWPs or WACs to the programs, and thus could not be used by states to change the reimbursement for Dey's drugs. See Henderson Exhibits cited in response to No. 156 above.

Additionally, the July 16, 2001 letter to the Texas Medicaid agency that Dey cites in support of its SOF No. 157 was sent nearly ten months *after* Texas had filed its *second* amended complaint against Dey based upon its falsely inflated WACs. (Henderson Ex. 142) (Second Amended Petition of the State of Texas Against Dey, Inc., Roxane Laboratories, Inc., and Warrick Pharmaceuticals Corporation).

158. Carolyn Helton of CIGNA, one of the DMERCs, also recalled receiving letters from Dey but did not call Dey in response. (Reid Decl., Ex. 153, at 117:1-118:8.)

The United States' Response: The United States that Ms. Helton testified as indicated, but disputes that such testimony is material or admissible; indeed, Ms. Helton did not call Dey in response to Dey's letters; she shredded them. (Reid Decl., Ex. 153, at 117:11 - 117:17.)

159. The Medicare system was enacted in 1965 as part of Title XVIII of the Social Security Act. Medicare is a health insurance program for people over the age of 65, people with certain disabilities, or people with End-Stage Renal Disease. Medicare Part A, also known as hospital insurance, helps cover inpatient care in hospitals. Medicare Part B, also known as medical insurance, helps cover doctors' services and outpatient care, and includes coverage for durable medical equipment and specific drug products. (Reid Decl., Ex. 13, at ¶¶ 24-25.)

The United States' Response: The United States does not dispute Dey's SOF No. 159.

160. Medicare Part B generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (see 42 C.F.R. § 410.26 (2009) (e.g., certain oncology drugs)); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. (see 42 C.F.R. § 405.517 (2009); Reid Decl., Ex. 13, at ¶ 26.)

The United States' Response: The United States does not dispute Dey's SOF No. 160.

161. Ensuring beneficiary's access to necessary medical care is a goal of the Medicare program. "The DRA requires CMS to ensure that Medicare and Medicaid beneficiaries continue to have access to high-quality medical care in the most appropriate setting." (Reid Decl., Ex. 154, at 11.)

The United States' Response: The United States does not dispute the statement and accuracy of the quoted language insofar as it describes the Deficit Reduction Act of 2005, Pub. L. 109-171, 120 Stat. 4 (enacted February 8, 2006). As Dey's statement appears confined to that statute, the United States does not respond further.

162. The Medicare program is administered by the federal agency CMS -formerly HCFA. During the relevant time period, CMS contracted with private insurance carriers to administer and pay Part B claims from the Medicare Trust Fund. In this capacity, the carriers act on behalf of CMS. (See 42 U.S.C.A. § 1395u (2009); 42 C.F.R. § 421.5(b) (2009); Reid Decl., Ex. 13, at ¶¶ 10, 25, 27.)

The United States' Response: The United States does not dispute Dey's SOF No. 162.

163. Originally, CMS contracted with fiscal intermediaries to process drug claims submitted by providers for drugs covered under Medicare Part B. However, in 1993,increased utilization of drugs used with durable medical equipment and the existence of unique provider groups led HCFA to create a system with separate fiscal intermediaries to process DME related claims. HCFA created four regions, each with a separate fiscal intermediary. The regional fiscal intermediaries are referred to as Durable Medical Equipment Regional Carriers ("DMERCs"). These institutions are not the same carriers as those that handle other Medicare payments. (Reid Decl., Ex. 47, at 1-2; Bradford ¶ 32.)

The United States' Response: The United States disputes the second sentence as unsupported and inconsistent with official HHS statements at 58 Fed. Reg. 60789 (November 18, 1993); 57 Fed. Reg. 27290 (June 18, 1992); (Henderson Exhibit 143, at 4-5.) (HHS OIG report, *DMERCs – Meeting HCFA's Objectives*, OEI-04-97-00330 (February 2000).

164. Dey's inhalation therapy Subject Drugs at issue in the Government's Medicare claim are all administered via a nebulizer which is classified as durable medical equipment and covered under Medicare Part B. Reimbursement for these drugs is processed through the DMERCs. (Reid Decl., Ex. 13, at ¶¶ 26-29).

The United States' Response: The United States does not dispute Dey's SOF No. 164.

165. Carriers and DMERCs are agents of CMS, and one way in which CMS/HCFA communicated its directives to the Carriers and DMERCs was through Program Memoranda. The DMERCs would use the program memoranda to set their reimbursement levels. (Reid Decl., Ex 13, at ¶ 27; Reid Decl., Ex. 155, at 107:20-109:6; Reid Decl., Ex. 153, at 126:10-18,139:22-140:11; Reid Decl., Ex. 156, at 144:18-145:3.)

The United States' Response: The United States does not dispute Dey's SOF No. 165, except that, with regard to the statement "Carriers and DMERCs are agents of CMS," the statement is true only to the extent of the delegation of authorities and functions from CMS to the Carriers and DMERCs.

166. The government established four DMERCs which cover four separate regions. (See 42 C.F.R. § 421.210 (2009); Reid Decl., Ex. 49, at 1-2; Bradford ¶ 32.)

The United States' Response: The United States does not dispute Dey's SOF No. 166.

167. Medicare generally reimburses for covered prescription drugs by using a 5-digit alphanumeric code, the Healthcare Common Procedural Coding System ("HCPCS" or "HCPCS Code"). (Reid Decl., Ex. 13, at ¶ 33.)

The United States' Response: The United States does not dispute Dey's SOF No. 167.

168. Unlike NDC codes, the HCPCS are not unique to product size, packaging or dose. A single HCPCS code can encompass more than one NDC, and therefore may include the products of different generic manufacturers selling similar multi-source drugs. (Reid Decl., Ex. 157, at 2-3.)

The United States' Response: The United States does not dispute Dey's SOF No. 168.

169. Medicare drug payments are not made for individual NDCs. Similarly, payment levels are not determined solely on individual NDC prices. Instead, payment levels are set at the procedural, or HCPCS, level. Thus for multi-source drugs, CMS uses the published prices available to set the reimbursement level for all drugs included in the HCPCS. Many manufacturers' products may be included in any one HCPCS code. (Reid Decl., Ex. 157, at 2-3.)

The United States' Response: The United States does not dispute Dey's SOF No. 169, except that the second sentence is an over-statement. During the relevant period a payment level could be determined solely on the basis of a single NDC price if there was only one NDC fitting the description of the HCPCS code. (Henderson Common Ex. 3 (Declaration of Carolyn Helton, Exhibit A, first page).)

170. To determine the ingredient payment level, the DMERCs collected AWPs for NDCs relevant to each HCPCS from pricing compendia. This list of NDCs and prices was commonly known as the pricing array. Each DMERC compiled a pricing array for each HCPCS on a quarterly basis and calculated the median generic or lowest brand price to determine the allowed reimbursement level. (Reid Decl., Ex. 158, at 272:1-277:19; Reid

Decl., Ex. 159.)

The United States' Response: The United States does not dispute Dey's SOF No. 170 generally. However, sometimes a DMERC would not create a new array if pricing information for a HCPCS code did not change; in that instance the DMERC simply relied on the prior array. (Henderson Ex. 144, at 221.)(Helton, 3/13/2008, p. 221) In addition, the description in the third sentence is imprecise. A better description is set forth at in the Declaration of Carolyn Helton. (Henderson Common Ex. 3.)

171. Although payment policies for Medicare Part B are set at the Federal level, regional DMERCs had exercised discretion in implementing these policies. Carolyn Helton of CIGNA testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Reid Decl., Ex. 153, at 151:7-17; Bradford ¶ 33.)

The United States' Response: The United States does not dispute Dey's SOF No. 171, except that the discretion of the DMERCs was constrained by HCFA and CMS instructions.

172. Because various DMERCs used their discretion to compile data for the arrays, there are differences in the prices listed in the arrays across DMERCs. Cheryl Eiler of Administar Federal, one of the DMERCs, testified: "We would try to use the products that best suited the narrative description of the HCPCS code that we were given in order to calculate the fee. And sometimes other regions may have used a different product than I would have used, and that would be the discrepancy, or used a different package." (Reid Decl., Ex. 292, at 426:20-427:-4; Bradford ¶ 33.)

The United States' Response: The United States does not dispute the testimony or that there were occasional differences among the DMERCs in the selection of products to be included in an array. (There is no evidence that DMERCs listed different prices for the same NDC.) However, the United States disputes the materiality of this statement to the issues presented by the motions for summary judgment.

173. The four regional DMERCs began to coordinate with each other on the construction of the quarterly pricing arrays. (Reid Decl., Ex. 158, at 300:4-304:5; Reid Decl., Ex. 155, at 153:1-17.)

The United States' Response: The United States does not dispute that, beginning in approximately 1997, the four DMERCs coordinated on a quarterly basis to maximize national consistency. (Henderson Common Ex. 3 (Helton Decl.) ¶ 9.)

174. Throughout the period at issue, Medicare would only use the AWP basis if it were lower than the provider billed charge. (See 42 C.F.R. § 405.517 (2009); Reid Decl., Ex. 160; Reid Decl., Ex. 161; Reid Decl., Ex. 162, at 192:17-195:3; Reid Decl., Ex. 163, at 325:1-7.)

The United States' Response: The United States does not dispute that, throughout the relevant period, Medicare paid on the basis of the lower of the fee calculated by the carrier (which was based on AWP) or the amount submitted by the provider in the claim.

175. From 1992 to 1997, the Medicare ingredient reimbursement formula was the lower of (1) the billed charge from the provider, or (2) the lower of the Estimated Acquisition Cost ("EAC") or the median AWP of all of the generic forms of the products in the relevant code. (Reid Decl., Ex. 164; Reid Decl., Ex. 162, at 192:17-195:3; Reid Decl., Ex. 163, at 325:1-7.)

The United States' Response: The United States does not dispute Dey's SOF 175, subject to paragraph 176 below, the United States' response to paragraph 169 above, and the fact that the AWP of the brand drug would be used if there was no published price for a generic form of the drug.

176. According to the Medicare regulations, EAC was to be based on surveys of actual invoice prices paid by providers. These surveys would have provided a basis of reimbursement independent of manufacturer published prices. In practice, the EAC component of Medicare Part B drug reimbursement allowable was never utilized. Instead, AWP published in the Red Book was used to determine the median AWP among all the generic multi-source drugs relevant to the HCPCS. (Reid Decl., Ex. 164; Reid Decl., Ex. 165, at

79:8-15; Reid Decl., Ex. 166, at 54:5-55:2; Reid Decl., Ex. 49, at 10; Reid Decl., Ex. 167, at 338:4-339:15.)

The United States' Response: The United States disputes the second sentence of Dey SOF #176 as unsupported by evidence. Responding further, it appears that the surveys contemplated by the regulations would not have provided a workable basis of reimbursement due to the expense of conducting reliable nation-wide surveys for all covered drugs on an on-going basis and the inability of such surveys to provide updated prices in a dynamic market.

177. In 1996 and 1997, the OIG published four reports which demonstrated that the acquisition costs for the Dey Subject Drugs were far below AWP: (1) "Medicare Payments for Nebulizer Drugs" OEI-03-94-00390 (February 1996) (Reid Decl., Ex. 47); (2) "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996) (Reid Decl., Ex. 48); (3) "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996) (Reid Decl., Ex. 49); and (4) "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290 (December 1997) (Reid Decl., Ex. 50).

The United States' Response: The United States does not dispute that OIG published the four reports cited in Dey SOF No. 177. The United States disputes Dey's characterization of the reports, and disputes that the reports are material, as there is no evidence that any Dey employee ever read any of the reports or relied upon them in making price-reporting decisions. See US-D-SF ¶¶ 180-199. The United States disputes the statement with regard to OEI-03-97-00290 and OEI-03-94-00390, inasmuch as those reports did not examine actual acquisition costs. The United States incorporates its response to No. 117 above.

178. In 1997, Congress refused to implement a portion of the Balanced Budget Act, the Medicare reimbursement proposal by President Clinton which would reimburse for prescription drugs at actual acquisition cost with an increase in dispensing fee. (Reid Decl., Ex. 168; Reid Decl., Ex. 169, at 181:5-182:21.)

The United States' Response: The United States disputes Dey's characterization of legislative history. Further, the content of a bill proposed by the President and the action or inaction of Congress are matters documented in the formal legislative record, which Dey has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

179. In 1998, the OIG published two reports which examined the acquisition costs for the Dey Subject Drugs, finding them to be far below AWP: "Are Medicare Allowances for Albuterol Sulfate Reasonable?" OEI-03-97-00292 (August 1998) (Reid Decl., Ex. 46); and "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293 (November 1998) (Reid Decl., Ex. 51).

The United States' Response: The United States does not dispute that OIG published in 1998 the two reports referred to in Dey SOF No. 179. The United States disputes Dey's characterization of the reports, and disputes that the reports are material, as there is no evidence that any Dey employee ever read any of the reports or relied upon them in making price-reporting decisions. See US-D-SF ¶¶ 180-199.

180. In January 1998, Congress changed the reimbursement formula to the lesser of the billed charge or 95 percent of the median AWP for drugs within a single HCPCS code. This information was transmitted to carriers and DMERCs in a Program Memoranda dated January, 1998 which states: "Effective January 1, 1998, pay for drugs and biologicals not paid on a cost or prospective payment basis at the lower of the billed charge or 95 percent of the AWP. This change in payment allowance recognizes the fact that the AWP is not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary. Part B deductible and coinsurance requirements apply." (Reid Decl., Ex. 160; Reid Decl., Ex. 161.)

The United States' Response: The United States does not dispute that Congress changed the Medicare reimbursement formula in 1998. The United States does not dispute that CMS

issued a Program Memorandum which contained the quotation above. The United States incorporates by reference its response to Dey SOF No. 121 above.

181. President Clinton again proposed a change in his Balanced Budget Act of 1998 to actual acquisition cost, but Congress once again did not adopt the actual acquisition cost methodology proposed by President Clinton and instead continued reimbursement based on 95% of AWP. (Reid Decl., Ex. 170.)

The United States' Response: The United States disputes Dey's characterization of legislative history. Further, the content of a bill proposed by the President and the action or inaction of Congress are matters documented in the formal legislative record, which Dey has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004). The United States the relevance of Dey's statement, as there is no evidence that Dey relied on the stated events during the relevant period in setting prices for Dey's drugs.

182. Former HCFA Administrator Nancy-Ann DeParle testified as follows:

Q. . . . HCFA had, in fact, included a provision in the President's 1998 Budget Bill, or the President included the provision in that budget bill, that would have eliminated the mark-up of the drugs billed by Medicare by requiring physicians to bill the program the actual acquisition costs. Do you see that?
A. Yes, I do.
Q. Do you recall that that was, in fact, included in the President's proposed budget for 1998?
A. Yes.
Q. And Congress chose not to enact that provision; correct?
MS. YAVELBERG: Objection; form.
A. It was not enacted.
Q. I mean, Congress did not enact the provision; right?
A. That's correct.
Q. Congress instead enacted the provision providing for a payment at 95 percent of AWP; right?
A. Yes.

Q. And requiring it to pay at 95 percent AWP; correct?
A. Yes.

(Reid Decl., Ex. 169, at 134:1-135:5.)

The United States' Response: The United states incorporates by reference its response to No. 181 above. The United States does not dispute that Nancy Ann-Min DeParle gave the above-quoted testimony.

183. CMS has consistently defined AWP as "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan" in its instructions to carriers. (Reid Decl., Ex. 160; Reid Decl., Ex. 171; Reid Decl., Ex. 172; Reid Decl., Ex. 173; Reid Decl., Ex. 174.)

The United States' Response: The United States disputes Dey's SOF No. 183. CMS has never defined AWP (except to the extent stated in 42 C.F.R. § 405.517(b)), and the cited documents do not show otherwise. The documents cited by Dey simply show that CMS used sources such as the Red Book, Blue Book, or Medispan as the source of AWP price information. The United States disputes any suggestion that CMS defined AWP to mean any number that the manufacturer chose to report without regard to actual prices generally and currently paid in the market.

184. The OIG issued another report studying the acquisition costs for the Dey Subject Drugs in January, 2001, "Medicare Reimbursement of Prescription Drugs" (Reid Decl., Ex. 53.)

The United States' Response: The Unites States disputes Dey's SOF No. 184. The referenced OIG report did not mention Dey or any of the NDCs at issue in this case. Further, the cost information used by the OIG consisted of catalog price information and acquisition cost information from the Department of Veterans Affairs. The United States further disputes any

implication that the referenced report evidences approval of Dey's false price reporting conduct. In the report, the HHS OIG characterized Medicare payments for certain drugs to be "excessive," and stated that Medicare "simply pays too much for prescription drugs" and that HCFA should continue to seek remedies "to reduce excessive drug reimbursement amounts." Report at p. 10. The United States incorporates by reference its response to Dey SOF No. 122 above.

185. From 1999 to 2003, regulations mandated that Medicare reimburse Part B covered drugs at 95 percent of the lower of the median published AWP for all generic forms of the drug or the AWP of the least expensive brand-name drug. (See Reid Decl., Ex. 175; Reid Decl., Ex. 176.)

The United States' Response: The United States does not dispute Dey's SOF No. 185, except that the method of reimbursement was extant from 1999 *through* 2003.

186. Program Memoranda AB-98-76 implemented these regulations and instructed carriers and DMERCs to calculate the median AWP as "the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP." (Reid Decl., Ex. 171.)

The United States' Response: The United States does not dispute Dey's SOF No. 186.

187. CMS continuously restated this formula for calculating the median AWP by issuing a September 1999 Program Memorandum, a November 14, 2000 Program Memoranda, and a May 22, 2002 Program Memoranda instructing Carriers and DMERCs to use AWP as set forth in the compendia and to calculate AWP by comparing the generic median with the lowest brand name product AWP. (Reid Decl., Ex. 172; Reid Decl., Ex. 173; Reid Decl., Ex.175.)

The United States' Response: The United States does not dispute Dey's SOF No. 187, except for the word "continuously."

188. The United States' 30(b)(6) designee, Donald Thompson, testified that CMS "develops

Medicare Part B payment policy through notice and comment rule making. And the policies would be contained in the rule making documents. The agency issued operational instructions to its claim processing contractors with respect to implementing those policies." (Reid Decl., Ex. 177, at 246:17-247:1.)

The United States' Response: The United States does not dispute Dey's SOF No. 188.

189. Mr. Thompson defined operational instructions to include the program memoranda sent to DMERCs and Carriers. (Reid Decl., Ex. 177, at 67:8-18.)

The United States' Response: The United States does not dispute Dey's SOF No. 189.

190. During 2004, regulations mandated that Medicare reimburse at a percentage of AWP dictated by statute, which, for the Dey Subject Drugs, was 80 percent. (Reid Decl., Ex. 178.)

The United States' Response: The United States does not dispute Dey's SOF No. 190.

191. CMS has the authority to adjust Medicare reimbursement payments that are not "inherently reasonable." 42 U.S.C.A. § 1395u(b)(8) (2009). This provision is known as the 'inherent reasonableness' clause. (Reid Decl., Ex. 179, at 2-4; Reid Decl., Ex. 55.)

The United States' Response: The United States does not dispute that CMS has the authority to reduce payments for a covered item or service if it determines that the statutorily defined payment amount is grossly excessive or deficient and therefore not "inherently reasonable."

192. In 1998, in response to the inherent reasonableness clause, the DMERCs surveyed the prices paid by providers for several products, including albuterol sulfate, reimbursed under Medicare Part B. (Reid Decl., Ex. 179, at 3-5; Reid Decl., Ex. 55.)

The United States' Response: The United States does not dispute that in 1998, the DMERCs surveyed retail prices for eight groups of products that were suspected to have

excessive Medicare payment rates, including albuterol inhalation solution administered through durable medical equipment.

193. As a result of the survey the internal medical director for region D recommended that an "… Inherent Reasonableness reduction of 15% in 1998 for albuterol sulfate 0.083% is clearly warranted and supportable." (Reid Decl., Ex. 180, at 0216.)

The United States' Response: The United States does not dispute Dey's SOF No. 193

194. In 1999, Congress passed legislation prohibiting HCFA from using the inherent reasonableness clause until the GAO conducted a study to examine the HCFA's effort. Among the questions posed by Congress for the GAO study was the issue of access due to the proposed reduced reimbursement levels. (Reid Decl., Ex. 179, at 2-3.)

The United States' Response: The United States does not dispute Dey's SOF No. 194, but notes that in its July 2000 report titled "Use of Revised 'Inherent Reasonableness' Process Generally," (GAO/HEHS-00-79), the GAO did not render an opinion on whether reducing Medicare payment for albuterol sulfate would negatively impact beneficiary access.

195. On September 8, 2000, CMS issued a program memorandum which announced alternative AWPs calculated "from wholesalers' catalogs that list the prices at which the wholesaler sells the respective products." (Reid Decl., Ex. 181.)

The United States' Response: The United States does not dispute that the Program Memorandum appended to the Declaration of Sarah Reid as Exhibit 181, on its face, indicates that its effective date was September 8, 2000. The United States does not dispute that the partial excerpt quoted above appears on page one of the three page (exclusive of attachments) memorandum.

196. According to the program memorandum "[t]he DOJ has indicated that these are more accurate wholesale prices for these drugs. Furthermore, the DOJ has indicated that because purchasers often receive further discounts below the advertised wholesale catalog price, either from a wholesaler or from the drug manufacturer directly, actual acquisition costs may be lower. The DOJ indicates that some physicians and suppliers obtain drugs at prices lower than the wholesale catalog prices through Group Purchasing Organizations (GPO)." (Reid Decl., Ex. 181.)

The United States' Response: The United States does not dispute that the partial excerpt quoted above appears on page one of the three page (exclusive of attachments) memorandum appended to the Declaration of Sarah Reid as Exhibit 181.

197. The revised AWPs included the specific example of albuterol: "For example, the DOJ data from wholesale catalogs indicates an average wholesale price of $22 for one albuterol sulfate NDC which is substantially less than the $73 average wholesale price in the Redbook and compares to $15 from a GPO. These data are generally consistent with findings from OIG reports." (Reid Decl., Ex. 181.)

The United States' Response: The United States does not dispute that the partial excerpt quoted above appears on page one of the three page (exclusive of attachments) memorandum appended to the Declaration of Sarah Reid as Exhibit 181. The United States disputes that the excerpt or information set out therein are material to this case.

198. CMS issued lower revised AWPs for Dey's then current albuterol NDCs and Dey's then current cromolyn NDCs. (Reid Decl., Ex. 181.)

The United States' Response: The United States disputes that "CMS issued lower revised AWPs." The Memorandum, on its face, indicates that the information appended to the document was being provided as data for carriers "to consider in determining the Medicare payment allowances for [the] January 2001 quarterly update."

199. An internal document shows that HCFA estimated that these lower prices would result in savings of roughly $650 million out of the total $1.8 billion in expenditures on drugs with a DOJ revised AWP – as potential savings of just over 36%. The agency documents further states that "[w]hile we believe that Medicare overpays for the drugs identified by DOJ, we must also assure continued beneficiary access to these drugs." (Reid Decl., Ex. 182.)

The United States' Response: The United States disputes Dey's SOF No. 199. There is no evidence that: the draft "internal document" was ever reviewed or approved by HCFA; that the rough savings estimate was ever verified; or that the conclusions purportedly stated in the memorandum were ever adopted by HCFA. The United States disputes that either the draft document or the quoted text are material to this case. The Government does not dispute that the draft internal document exists and was produced to defendants.

200. Nancy-Ann DeParle, HCFA Administrator in 2000, testified that she personally suspended these lower AWPs for certain drugs. (Reid Decl., Ex. 169, at 294:4-21.)

The United States' Response: The United States disputes Dey SOF No. 200. Ms. DeParle neither established nor suspended AWPs for any drugs. To the extent that this paragraph refers to the instructions in the Septmember 2000 HCFA Program Memorandum, that Memorandum, on its face, indicates that the information appended to the document was being provided as data for carriers "to consider in determining the Medicare payment allowances for [the] January 2001 quarterly update." More specifically, Ms. DeParle testified that because cancer and hemophilia patients and oncologists had claimed that drugs could not be purchased at the prices that were listed in the DOJ data, she made the determination that the DOJ pricing data should not be used for chemotherapy or hemophilia drugs until HCFA had done more work on them to verify that physicians could obtain the drugs at those prices. Thus, for these types of

drugs, the DOJ pricing data was never used and thus such use was never suspended. Furthermore, although Ms. DeParle was HCFA Administrator during 2000, she left that position and HCFA in September or October of that year.

201. Ms. DeParle testified that she "couldn't and would not risk a cancer patient not being able to get his or her chemotherapy." (Reid Decl., Ex. 169, at 287:9-11.)

The United States' Response: The United States does not dispute that the partial excerpt quoted above appears on page 287 of Ms. DeParle's deposition testimony appended to the Declaration of Sarah Reid as Exhibit 169. However, Ms. DeParle's full testimony in response to the posed question was that she both wanted Medicare to run as efficiently as possible and wanted to be sure that cancer patients would be able to get their chemotherapy. The United States disputes that the excerpt or information set out therein are material to this case. None of the Subject Drugs are chemotherapy drugs.

202. On November 17, 2000, a little over two months after they were first announced, Medicare suspended use of all DOJ AWPs, stating "[w]hile we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source." (Reid Decl., Ex. 183.)

The United States' Response: The United States does not dispute that the Program Memorandum appended to the Declaration of Sarah Reid as Exhibit 183 contains the quoted language. The United States disputes that the excerpt or information set out therein are material. The United States further incorporates by reference its statements at US-C-SF ¶¶ 17-20.

203. In 2005, Medicare began reimbursing providers for the ingredient cost based on a markup

(106 percent) over the Medicare ASP. (See 42 U.S.C.A. § 1395w-3a (2009).)

The United States' Response: The United States does not dispute Dey's SOF No. 203, except that this statement is a very simplistic characterization of the change in the Medicare drug reimbursement scheme, as well as being immaterial.

204. The change in reimbursement formula from 95% of AWP to 106% of ASP resulted in lower payments for the ingredient cost of drugs. Donald Thompson, the Government's 30(b)(6) witness, testified that the payment rate that was developed under the ASP resulted in payments that were lower than the payments that were made under the prior system. (Reid Decl., Ex. 177, at 274:10-15.)

The United States' Response: The United States does not dispute the statement, but does dispute its materiality.

205. Prior to reforms introduced in 2005 under the MMA, the dispensing fee allowed for inhalation drugs was $5.00. (Reid Decl., Ex. 177, at 272:18-273:7.)

The United States' Response: Undisputed.

206. Once ASP methodology was implemented, the drug dispensing fee for inhalation drugs was to be increased from $5 to a $57 monthly fee (or $80 90-day fee), effective in 2005. (Reid Decl., Ex. 184; Reid Decl., Ex. 185.)

The United States' Response: The United States disputes any implication that changes in Medicare dispensing fees after 2003 are relevant or material to this action. The United States further disputes Dey's characterization as incomplete and misleading. In an interim rule published at 69 Fed. Reg. 66236, 66337-66342, 66412-66413, 66425 (Nov. 15, 2004), CMS established on an interim basis, for 2005 only, a dispensing fee of $57 for each dispensed 30-day supply of inhalation drugs, regardless of the number of partial shipments of that 30-day supply,

and an $80 fee for each dispensed 90-day supply, regardless of the number of partial shipments of that 90-day supply. After studies and analyses indicated that these dispensing fee levels exceeded actual dispensing costs, *see* 70 Fed. Reg. 45847 (August 8, 2005) (proposed rule), CMS promulgated a final rule, published at 70 Fed. Reg. 70116 (November 21, 2005), which provided that Medicare will pay a dispensing fee of dispensing fee of $57 to the extent that the prescription is for the initial dispensed 30-day supply, regardless of the number of partial shipments of that 30-day supply, and a dispensing fee of $33 for each subsequent dispensed 30-day supply, regardless of the number of partial shipments of that 30-day supply. The regulation further provides for a payment of $66 to a supplier for each dispensed 90-day supply of inhalation drugs. 42 C.F.R. § 414.1001 (2009). The net result is an average dispensing fee of about $35.

207. The Medicaid program was signed into law in 1965 as part of Title XIX of the Social Security Act and is a joint federal-state program that provides medical assistance to financially needy patients. (See 42 U.S.C.A. § 1396-1 (2009).)

The United States' Response: The United States does not dispute the statement, but clarifies that Medicaid is a federal-state program to assist the poor, elderly, and disabled in obtaining medical care, and does not provide medical services itself. 42 C.F.R. § 430.0 (2009). Under the Medicaid Act, which is Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 - 1396v, the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by HHS. 42 U.S.C. § 1396; 42 C.F.R. §§ 430.0, 430.10 - 430.20 (2009).

208. The Medicaid program is jointly funded by states and the federal government. The federal government pays for a share of each state's Medicaid program expenditures which ranges from 50% to 83%. (See 42 U.S.C.A. § 1396d(b) (2009).)

The United States' Response: The United States does not dispute Dey's SOF No. 208.

209. In 1987, CMS, then known as the Health Care Financing Administration ("HCFA"), after a Task Force report and recommendation, enacted regulations 42 C.F.R §§447.301 to 447.333.

The United States' Response: The United States does not dispute that HCFA enacted the regulations cited above in 1987, but note that the notice of final rulemaking only references concerns expressed to a task force and does not reference either a task force report or recommendation. 52 Fed. Reg. 28648 (July 31, 1987).

210. CMS provides individual states substantial discretion in designing their Medicaid programs. (See 42 C.F.R § 447.502 (2009); See 42 C.F.R § 447.302 (2009); See 42 C.F.R § 447.304 (2009); See 42 C.F.R § 447.512 (2009); See 42 C.F.R § 447.514 (2009); See 42 C.F.R § 447.518 (2009).)

The United States' Response: The United States objects to Dey's attempt to use LR 56.1 as a vehicle to describe its view of the law or obtain admissions by the United States on matters of law.

211. State Medicaid agencies must act in accordance with their State Plan, which CMS reviews and approves annually. (See 42 C.F.R § 447.201 (2009); See 42 C.F.R § 447.518 (2009); Reid Decl., Ex. 13, at ¶ 20.)

The United States' Response: The United States objects to Dey's attempt to use LR 56.1 as a vehicle to describe its view of the law or obtain admissions by the United States on matters of law. Further, the regulations and exhibit cited by Dey do not reference annual review and approval of state plans. Finally, to the extent Dey suggests that it has standing to complain about a possible discrepancy between a State's actual reimbursement practice and the State's State

Plan, Dey is wrong. *Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50 (1st Cir. 2004).

212. However, within the broad federal requirements set by CMS, states have considerable flexibility in designing their State Plans. (Reid Decl., Ex. 186, at 431:4-9; Reid Decl., Ex. 187, at HHC002-0565.)

The United States' Response: The United States does not dispute that States have flexibility in designing their State Plans, although the United States notes that the testimony and exhibit cited by Dey do not even mention state plans. Moreover, although States have flexibility, in practice virtually all States have implemented drug reimbursement methodologies that use a "lower of" methodology that uses Estimated Acquisition Cost (EAC) as a basis for determining drug payments. All States use published prices to determine EAC. No State delegates to drug manufacturers the right to determine the level of profit that providers might receive. No State has established a methodology providing that EAC is equal to whatever price the manufacturer chooses to report regardless of whether it is moored to actual transaction prices. The United States refers the Court to its Common Statement of Facts, US-C-SF at ¶¶ 29-34.

213. In 1989, Fred Schutzman, the Director, Bureau of Quality Control of HCFA requested that all HCFA regional administrators conduct a survey of each state's drug reimbursement policies using an attached survey form. The Glossary for the survey, dated March 23, 1989, defines "Average Wholesale Price" as "Published prices from Red Book, Blue Book or Medi-span. These are wholly fictitious prices similar to the sticker price on a new car." The surveys were completed at the regional level and returned to HCFA. (Reid Decl., Ex. 188, at HHD0084-0010.)

The United States' Response: The United States disputes Dey's SOF No. 213 insofar as the exhibit cited does not show that all surveys were completed at the regional level and returned

to HCFA. The United States disputes the relevance of the report to Dey's liability under the FCA. First, the report does not mention Dey or refer to any of the drugs at issue in this litigation. Second, Dey has offered no evidence that Dey ever saw this document or relied on its contents in setting prices for Dey drugs. Third, the report does not suggest, as Dey seems to imply, that Mr. Schutzman approved of the reporting of fictitious prices.

214. Bruce Vladeck, Administrator of CMS from 1993 to 1997, testified that states had leeway to be able to determine the specific ingredient reimbursement basis that they wanted, as long as it was acceptable to the federal government, and the government approved a variety of reimbursement methods that were consistent to federal law. (Reid Decl., Ex. 35, at 433:8-449:12.)

The United States' Response: The United States disputes Dey's characterization of Mr. Vladeck's testimony. The United States incorporates its response to No. 213 above.

215. Mr. Vladeck testified as follows:

A. HCFA approved state plans that paid on some basis relative to AWP, because that's what the statute provided for.

Q. And in doing that you were approving plans that had the spread built into the reimbursement methodology. Right?

MS. BROOKER: Objection. Form.

A. Again, I would say that had a spread built into the reimbursement methodology.

Q. Fine. But you also had one state, at least, that had no spread.

Right?

MS. BROOKER: Objection. Form.

MR. BREEN: Objection. Form.

A. Yes, that's correct.

(Reid Decl., Ex. 35, at 448:21-449:12.)

The United States' Response: The United States does not dispute that Mr. Vladeck testified as set forth above, but notes that Mr. Vladeck also testified that he was not competent to testify as to the size of the spread. (Reid Decl., Ex. 35, at 447:10-14.) The United States incorporates its response to No. 213 above.

216. Thomas Scully, Administrator of CMS from 2001 to January 2004, testified that it was CMS's policy to let the states make their own determination of what levels to reimburse providers at, and that it was up to the states' discretion whether they decided to reimburse at AWP minus 10% when CMS and the state knew that actual acquisition cost was more like AWP minus 40%. (Reid Decl., Ex. 189, at 209:11-210:15.)

The United States' Response: The United States disputes Dey's SOF No. 216 because it does not accurately summarize Mr. Scully's testimony. Mr. Scully testified that CMS sought to educate states regarding "reasonable prices." The United States also incorporates by reference its response to No. 213 above.

217. For multiple source drugs subject to an upper limit established by HCFA, the 1987 regulations limited payment in the aggregate, across all drugs, to the amount that would result from the application of the specific limits established by HCFA plus a reasonable dispensing fee. (Reid Decl., Ex. 190.)

The United States' Response: The United States disputes Dey's characterization of the 1987 regulations. The language of the regulation (at 52 Fed. Reg. 28648, 28657 (July 31, 1987)) controls, not Dey's characterization. Further, it is inappropriate for Dey to use a Rule 56.1 statement to advance its view of the law.

218. For all other drugs not subject to a Federal Upper Limit ("FUL"), a state agency's payment for all "other drugs" "must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) EAC plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public." (See 42 C.F.R. § 447.512(b) (2009).)

The United States' Response: See response to No. 217 above.

219. The regulations define "Estimated acquisition cost" to be a state agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." (See 42 C.F.R. § 447.502 (2009).)

The United States' Response: The United States does not dispute the accuracy of the quoted language.

220. A state agency's reimbursement methodologies are subject to an access constraint: "The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." (See 42 C.F.R. § 447.204 (2009).)

The United States' Response: The United States disputes Dey's SOF No. 220 because the regulation references actual "payments" to providers and not reimbursement methodologies.

221. Accordingly, state Medicaid agency personnel attempt to balance at least two competing goals when making policy decisions to set reimbursement rates: 1) achieve sufficient access to quality health care for the enrollees, and 2) administer the program within the budget constraints imposed by the state legislature. (Reid Decl., Ex. 191, at 108:3-109:13; Reid Decl., Ex. 192, at 307:13-308:5; Reid Decl., Ex. 140, at 464:3-465:7; Reid Decl., Ex. 193, at 49:10-51:18.)

The United States' Response: The United States disputes Dey's SOF 221 because the testimony from various state Medicaid employees does not support the characterization of these goals as necessarily "competing."

222. The Medicaid program controls costs by obtaining rebates from drug manufacturers and rebates factor into the rate set for prescription drugs. (Reid Decl., Ex. 38, at 4.)

The United States' Response: The United States does not dispute that the Medicaid controls its drug expenditures, in part, through the rebates received from drug manufacturers. The United States disputes any suggestion that rebates paid under the Medicaid Drug Rebate program are factored into the state Medicaid drug reimbursement formulas. Dey cites to no evidence in support of such a suggestion.

223. In addition, some states have entered into supplemental rebate agreements with manufacturers which require manufacturers to submit their AMPs to the state and pay an additional amount beyond what the manufacturers are already required to pay under the OBRA 90 rebate agreement. (Reid Decl., Ex. 33, at 667:9-668:5.)

The United States' Response: The United States does not dispute Dey SOF No. 223. The United States further notes that supplemental rebate agreements generally require that information submitted by the manufacturer shall be kept confidential and used solely for the purpose of administering the supplemental rebates. Dey itself has entered into such agreements and has marked its copy "HIGHLY CONFIDENTIAL." US-C-SF ¶¶ 105-106. Therefore, supplemental rebate agreements are not relevant or material.

224. For example, Texas Government Code § 531.070 regarding supplemental rebates states: "[i]n negotiating terms for a supplemental rebate, the commission shall use the average manufacturer price (AMP), as defined in Section 1396r-8(k)(1) of the Omnibus Budget Reconciliation Act of 1990, as the cost basis for the product." (See Tex. Gov't Code Ann. § 531.070(m) (Vernon 2009).)

The United States' Response: The United States does not dispute Dey's SOF No. 224, but disputes the materiality of the statement. The United States further incorporates its response

to No. 223 above.

225. State MAC programs have been in existence since the 1970s. For example, a MAC program has been in place since 1976 in Maryland. By the early 1990s, 22 states had MAC programs for generic drugs. The number of states with a MAC program has increased steadily over the past decade, and by 2005, there were 44 states that had enacted MAC programs. (Bradford Decl. ¶ 24.)

The United States' Response: The United States disputes Dey's SOF #225 as unsupported. Dey's expert Dr. Bradford provides no support for his assertions and appears to have no experience or qualifications to opine on the subject. Accurate information concerning State MAC programs is set forth in the United States' Common statements of fact, US-C-SF ¶¶ 32.

226. CMS encourages states to adopt state-specific MACs to respond to and benefit from competitive commercial discounting. (See Reid Decl., Ex. 194, at 28,653) ("We hope that the State agencies will be innovative in these programs and find ways to assure the availability at reasonable prices of multiple-source drugs… State agencies may initiate or retain already existing so-called 'mini-MAC' programs, which they have established on specific drugs either at levels lower than those established under the current Federal MAC limits or on drugs not now covered by MAC limits.").)

The United States' Response: The United States disputes Dey's characterization of the statements in the Federal Register as unsupported by the language and inaccurate. Nowhere in the document referenced by Dey did the agency state or imply that State MAC programs were intended "to respond to and benefit from competitive commercial discounting."

227. Of the states with claims data, 26 out of the 32 states had a state MAC in effect for some of the drugs at issue for some time period. (Bradford Decl. ¶ 25; Bradford Decl. Figure 7.)

The United States' Response: The United States disputes this Statement of Fact. Figure

48 to the Bradford declaration, if correct, has entries under the "state MAC" column for only 20 states excluding Ohio.

228. For the states for which Dr. Bradford had state-level claims data, approximately 8.8 percent of claims for the Subject Drugs for which there is claims data in the record are reimbursed on the basis of a state MAC. (Bradford Decl., Figure 5.)

The United States' Response: The United States disputes this Statement of Fact. Figure 48 to the Bradford declaration, if correct, indicates that only 6.02% of claims for the Subject Drugs were paid at state MAC with 4.98% represented by the 16 states for which Dr. Duggan re-adjudicated claims and only approximately 1% from the extrapolated-to states.

229. Much of the MAC data is missing or gone as a result of the Government's failure to preserve it while this case remained sealed for nine years. Dey hereby incorporates its Motion for a Finding of Spoliation and for Sanctions (Docket 6109), Memorandum of Law in Support of its Motion for a Finding of Spoliation and for Sanctions (Docket 6110), and supporting Declaration of Sarah L. Reid (Docket 6111).

The United States' Response: The United States objects to this purported statement of fact because it fails to comply with LR 56.1 which, in pertinent part, requires that the statement include page references to affidavits, depositions and other documentation. Defendant's statement broadly references multiple docket entries which contain briefs to which defendant appended thousands of pages of attachments. The statement is unduly vague and over-broad. Notwithstanding this objection, the United States disputes this statement. The grounds therefore are set out in the Memorandum by the United States in Opposition to Defendant's Motions for a Finding of Spoliation and for Sanctions. See Docket entry 6270 in 01-cv-12257 at p. 16-18, 21-33. Moreover, defendant's allegations regarding a the Government's purported failure to

preserve information held by the states is currently being addressed as a contested issue in briefs relating to pending motions. The United States also disputes that defendant's statement relates to a material issue in the motions for summary judgment.

230. There is substantial variation among state MAC programs. For example, Arkansas' state MACs are based on pharmacies' actual invoice prices, not AWPs or WACs. (Reid Decl., Ex. 192, at 65:3-11, 248:11-15, 250:9-251:4 ("[MACs] are based on what the pharmacy says they have paid for the product").)

The United States' Response: The United States does not dispute that there is variation among State MAC programs. Dey's characterization of the variation among state MAC programs as "substantial," however, is vague and unsupported by the cited authority.

231. Maine's MACs are based on pharmacies' acquisition costs ("the amount of money it costs the pharmacy to acquire a medication"). (Reid Decl., Ex. 195, at 94:5-98:3.)

The United States' Response: Undisputed.

232. Minnesota's MACs are based on actual acquisition costs that were provided by a group of pharmacies. (Reid Decl., Ex. 196, at 64:13-66:19.)

The United States' Response: Undisputed.

233. Wisconsin's MACs are based on wholesaler selling prices that are provided by wholesalers. (Reid Decl., Ex. 197, at 16:10-17:14, 61:3-64:22, 160:9-161:15.)

The United States' Response: The United States does not dispute that Wisconsin currently bases its MACs on pricing supplied by wholesalers. Further answering, Wisconsin used "a variety of sources over the years" to set MAC prices, including pricing supplied by wholesalers and others. (Reid Decl., Ex. 197, at 16:10-17:14, 61:3-64:22, 160:9-161:15.)

234. In Georgia, MACs are determined by pharmacy benefit managers who have their own proprietary methods for calculating the MACs, which they don't share with the State. (Reid Decl., Ex. 198, at 67:12-68:22, 207:3-13; 306:13-307:21.)

The United States' Response: The United States does not dispute that Georgia MACs are determined by a pharmacy benefit manager with whom the State contracts, and that the current and past pharmacy benefit managers have their own proprietary methods for calculating the MACs. Further answering, although the pharmacy benefit managers have not shared the precise method they used to calculate MACs, the State has provided guidance to its pharmacy benefit managers on how to set MACs, the State has insight into how the MACs are set, and the State has been provided information from its pharmacy benefit managers as to what the resulting prices are in the aggregate (AWP – 65% to 70%) and as compared to other pricing measures. (Reid Decl., Ex. 198, at 67:12-68:22, 207:3-13; 306:13-307:21.)

235. In all of the following states, MACs were based on acquisition costs, proprietary Medicaid agency formulas, private contractor data and calculations, provider invoices, or other methods that did not rely exclusively on the published prices for Dey's drugs: Alabama (Reid Decl., Ex. 271; Reid Decl., Ex.272; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Arkansas (Reid Decl., Ex. 192, at 65:3-11, 248:11-15, 250:9-251:4); California (after September 2002) (Reid Decl., Ex. 274, at 250:8-251:10); Connecticut (Reid Decl., Ex. 275, at 88:19-89:2); Florida (Reid Decl., Ex. 276, at 231:18-233:7); Georgia (Reid Decl., Ex. 198, at 67:12-68:12, 207:3-13; 306:13-307:21); Hawaii (Reid Decl., Ex. 277, at 392:22-393:3; 395:3-6); Idaho (Reid Decl., Ex. 278; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Illinois (after March 2005) (Reid Decl., Ex. 213, at 55:14-56:10; Reid Decl., Ex. 279, at 5-6; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Indiana (Reid Decl., Ex. 280, at 398:3-400:21; 652:12-653:15; Reid Decl., Ex. 281, at 134:21-135:12); Iowa (Reid Decl., Ex. 282; Reid Decl., Ex. 273, at 116:11-117:18, 119:18-120:16); Maine (Reid Decl., Ex. 195, at 94:5-98:3); Maryland (MAC program called the IDC program in Maryland) (Reid Decl., Ex. 216, at 201:14-205:12, 320:2-10); Michigan (Reid Decl., Ex. 283, at 37:14-39:9; Reid Decl., Ex. 144, at 49:4-9, 144:10-145:22); Minnesota (Reid Decl., Ex. 196, at 64:13-66:19); Missouri (Missouri has a "Missouri MAC" program) (Reid Decl., Ex. 284, at 38:12-25); Nebraska (Reid Decl., Ex. 145 at 130:10-134:10); Nevada (Reid Decl., Ex. 285, at 515:20-516:10,

524:4-8); New Hampshire (Reid Decl., Ex. 259, at 66:11-67:15, 169:15-170:3); North Carolina (Reid Decl., Ex. 146, at 261:6-266:2); North Dakota (Reid Decl., Ex. 220, at 96:21-98:12; 101:2-102:13; 112:21-113:21, 127:7-129:20); Ohio (Reid Decl., Ex. 221, at 158:1-161:18); Oregon (Reid Decl., Ex. 223, at 173:19-174:3, 177:18-21); South Dakota (Reid Decl., Ex. 225, at 98:19-99:14); Tennessee (Reid Decl., Ex. 148, at 106:18-109:11); Vermont (Reid Decl., Ex. 149, at 197:13-198:15); Washington (Reid Decl., Ex. 226, at 105:14-108:18); Wisconsin (Reid Decl., Ex. 197, at 15:21-17:14, 61:3-64:10, 74:9-18, 193:8-12, 199:1-10, 205:2-207:14); and Wyoming (Reid Decl., Ex. 227, at 233:19-234:16).

The United States' Response: For purposes of Dey's motion, the United States does not dispute that the listed State MAC programs used methods that did not rely "exclusively" on the published prices for Dey's drugs. However, at least some states have relied at least in part on published prices in setting their MACs. For example, Alabama (Reid Decl., Ex. 272); California (Henderson Ex. 148, at 451-452); Delaware (Henderson Decl., Ex. 138, at 463-466); Georgia (Henderson Decl., Ex. 128, at 35-36, 206-210); Hawaii (Henderson Ex. 145, at 446-448); Illinois (Henderson, Ex. 129); Louisiana (Henderson Ex. 146); North Carolina (Henderson, Ex. 132, at 46-49); and Ohio (Henderson Decl., Ex. 147, 154-162) have used published AWPs and/or WACs in setting their State MACs, and therefore it is likely that in these States at least, where State MACs applied to a Subject Drug, Dey's false price caused the MAC to be inflated. Dey's reference to the California MAC program, and possibly others, is misleading, as that program has been moribund since the early 1990s and Dey's drugs have never been subject to a California MAC, and the California MAC program did not change as Dey suggests in 2000; rather, in 2002 the California Legislature amended the MAC program to authorize the use of data provided by wholesalers; but wholesalers refused to provide the data, and that feature was never implemented. (Henderson Ex. 148 at 446-448.) Responding further, the United States disputes that the specifics of any State's MAC program are material to any issue presented in the summary

judgment motions. The Plaintiffs' theory of recovery and damages model are not based upon Dey's false price statements causing inflated MACs. Rather, the United States asserts that Dey's false price representations caused EAC to be inflated, and thereby caused damages whenever the original reimbursement amount – whether based on EAC, MAC, FUL, or U&C – was higher than it would have been but for the inflated EAC. All or nearly all States would have based reimbursement on EAC had it resulted in a lower amount. (Henderson Common Ex. 24 (Knerr Decl.) ¶ 18, 19, 24.) Moreover, to the extent State MACs have been established for any of the Subject Drugs, such MACs most probably would have been unnecessary had Dey reported truthful prices. *See, e.g.*, Henderson Ex. 149 (Affidavit of Ted Collins, Wisconsin Medicaid) ¶ 10.

236. The United States have failed to provide evidence that any of the following states set MACs based on published prices of Dey's drugs: Kansas, Mississippi, New York, South Carolina, and Utah.

The United States' Response: See response to paragraph 235 above.

237. The following states used published prices to set MACs, but The United States have failed to produce any evidence that Dey's published prices had any material effect on the amounts at which those MACs were set: Alabama (Reid Decl., Ex. 286, at 761:22-763:11); California (before September 2002) (Reid Decl., Ex. 274, at 216:11-217:14); Delaware (Reid Decl., Ex. 142, at 102:18-106:1, 127:8-132:2; Reid Decl., Ex. 143, at 404:8-14, 463:7-20); Illinois (before March 2005) (Reid Decl., Ex. 213, at 55:14-56:10; Reid Decl., Ex. 279, at 5-6); Kentucky (Reid Decl., Ex. 287); Louisiana (Reid Decl., Ex. 215, at 88:13-89:11); Massachusetts (Reid Decl., Ex. 288; Reid Decl., Ex. 289); New Mexico (Reid Decl., Ex. 219, at 286:2-287:8); Pennsylvania (Reid Decl., Ex. 290); and Virginia (Reid Decl., Ex. 150, at 33:18-34:18).

The United States' Response: See response to paragraph 235 above.

238. Federal Medicaid officials began to address the unique features of the generic market in the 1970s and 1980s through a Federal Maximum Allowable Cost program that placed ceilings on reimbursement levels for generic drugs. (Reid Decl., Ex. 199, at 32,297-98.)

The United States' Response: The phrase "began to address the unique features of the generic market" is ambiguous as used in this paragraph. The United States does not dispute that in 1975 HCFA published a final rule in the Federal Register establishing the Pharmaceutical Reimbursement Board ("PRB"), and specifying that reimbursement for all covered drugs should not exceed the lowest of a Maximum Allowable Cost (as established by the PRB) plus a reasonable dispensing fee; an estimate of the acquisition cost of the drug plus a reasonable dispensing fee; or the provider's usual and customary charge to the public for the drug. 40 Fed. Reg. 32284, 32302 (July 31, 1975). The paragraph is otherwise disputed, and is not supported by the cited authority.

239. In 1987, the federal government furthered its efforts to allow states to benefit from steep discounts in the generic market by adopting the FUL program expressly for the purpose of encouraging migration to lower-cost generic drugs. (Reid Decl., Ex. 200.)

The United States' Response: The United States does not dispute that in 1987, the United States Department of Health and Human Services promulgated regulations to establish aggregate upper limits of payment by Medicaid plans for multiple source and other drugs. Those regulations and the agency's description of the process for adopting them are contained in 52 Fed. Reg. 28,648 *et seq*. The stated purpose of the regulations was to address concerns with HHS' then-current reimbursement system and "to take advantage of savings that are currently available in the marketplace for multiple source drugs . . . ." (*Id.*) The statements in Dey SOF #239 are otherwise disputed and are not supported by the cited authority.

240. The FUL program was intended to "enable[] the Federal and State governments to take advantage of savings that are . . . available in the marketplace for multiple source drugs" while at the same time maintaining flexibility for states to determine their own reimbursement rates and to experiment with methods of furthering controlling the cost of offering Medicaid beneficiaries a prescription drug benefit. (Reid Decl., Ex. 201.)

The United States' Response: The United States does not dispute that the FUL program was adopted to enable "the Federal and State governments to take advantage of the savings that are currently available in the marketplace for multiple source drugs" and to maintain "State flexibility in the administration of the Medicaid program." 52 Fed. Reg. at 28,648. The United States does not dispute that under the "aggregate limits" of the FUL program, State agencies are free to experiment with alternative payment systems[.]" (*Id.*) The statements in this paragraph are otherwise denied and are not supported by the cited authority.

241. From 1987 to 2006, the FUL regulation provided that a state's reimbursement for multiple source drugs "in the aggregate" must not exceed 150% of the published price for the least costly therapeutically equivalent product where at least three suppliers market a given generic drug. (Reid Decl., Ex. 202.)

The United States' Response: Disputed. The FUL regulation referenced by Dey provided:

> The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by CMS that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in

> quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

242. CMS instituted FULs for Dey's albuterol unit dose, albuterol multi dose, 90MCG inhaler, and ipratropium bromide NDCs at issue during the time period at issue. (See Bradford Decl., Figure 6.)

The United States' Response: The United States does not dispute Dey's SOF No. 242.

243. For the states for which Dr. Bradford had state-level claims data, approximately 15.5 percent of claims for the Subject Drugs for which there is claims data in the record are reimbursed on the basis of the FUL. (Bradford Decl., Figure 5.)

The United States' Response: The United States does not dispute Dey's SOF No. 243, except the United States disputes that this paragraph has any relevance or materiality to its claims in this case.

244. CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet their dual objectives of cost savings and access. Despite regulations stating otherwise, CMS based FULs on prices that were not the lowest published prices. (Reid Decl., Ex. 203, at 225:16-226:7; Reid Decl., Ex. 204, at 73:14-74:22; Reid Decl., Ex. 255 at 428:10-20; Reid Decl., Ex. 202.)

The United States' Response: The United States objects to Dey's attempt to extract from the United States statements that are immaterial to any issue in the instant summary judgment proceedings in order to support Dey's defense in the *City of New York* litigation. Such a tactic is an abuse of LR 56.1, and the United States asks the Court to strike Dey's Statement Nos. 244-249. As Dey well knows, the United States in this case is not proceeding on a "FUL theory of liability," and therefore Dey's SOFs concerning the details of the FUL-setting process have no

bearing on the instant case.

The United States' further states that CMS utilized a program known as the Federal Upper Limit System ("FUL System") in setting FULs, and that the FUL System downloaded information from the FDA's Orange Book as well as information from pricing compendia to create listings of reported prices for drugs statutorily eligible for a FUL. (Henderson Ex. 150 at 232:18 - 234:18.) CMS employees then reviewed the price listings generated by the FUL System to ensure, among other things, that the drug would be available at the FUL price and that the FUL would generate cost savings to the federal government because it would be lower than the reported AWPs. (*Id*. at 456:6 - 457:6.) If the lowest published price appeared to be significantly lower than the next available published price, CMS employees contacted manufacturers to determine if the published price was valid and nationally available. In addition, CMS employees generally would not use a lowest published price if it resulted in a FUL that was not higher than at least three other published prices. (Henderson Common Ex. 40 ¶¶ 4-5.) Thus, it would appear, for example, that if defendants Dey and Roxane had reported truthful prices to the publishing compendia for ipratropium bromide, the FUL for that drug would have been lower. The paragraph is otherwise denied, and is not supported by the cited authority.

245. CMS conducts a manual review of proposed FUL prices to determine whether a drug was "truly available or not" and whether or not "you should follow up and see if it's available." (Reid Decl., Ex. 203, at 229:8-230:14.)

The United States' Response: The United States incorporates its objection, request, and response as set forth in its response to paragraph 244 above.

246. This manual review was implemented for the Dey albuterol drugs at issue in this motion. (See, e.g., Reid Decl., Ex. 204, at 89:2-5, 93:12-94:16; Reid Decl., Ex. 205, at 470:2-472:21, 474:7-16, 496:21-497:7.)

The United States' Response: The United States does not dispute that CMS employees reviewed FULs for Dey's albuterol drugs to determine if publishes prices were valid and nationally available, and to determine if the FUL was likely to generate cost savings to the federal government. Further answering, FULs were set based on published prices in the pricing compendia. The United States incorporates its objection, request, and response as set forth in its response to paragraph 244 above.

247. For example, Susan Gaston, CMS Heath Insurance Specialist, Pharmacy Division, and the person in charge of setting FULs at CMS, testified that CMS removed the FUL for the 90 MCG albuterol inhaler upon learning of a shortage of the drug's raw material because "if the product is not available then it wouldn't make sense to put a FUL price on it." (Reid Decl., Ex. 205, at 470:7-472:21.)

The United States' Response: The United States does not dispute that Ms. Gaston testified that CMS temporarily removed the FUL for the 90 MCG albuterol inhaler upon being told by persons outside CMS that there was a raw material shortage for the drug.

248. The FUL regulation does not establish a reimbursement rate for any drug, but affords the states flexibility in setting reimbursement rates for particular drugs so long as the state reimburses at or below the applicable FUL limitation. (See 42 C.F.R § 447.304 (2009); See 42 C.F.R § 447.512 (2009); See 42 C.F.R § 447.514 (2009); See 42 C.F.R § 447.518 (2009).)

The United States' Response: The United States does not dispute that because the federal upper limit standards were aggregate in nature, state Medicaid programs had "the ability to make payment at levels above the specific standard for certain drugs, provided that the agency makes

the payment at levels below the specific standard for other drugs." 52 Fed. Reg. 28,648. The paragraph is otherwise denied, and is not supported by the cited authority.

249. Dey hereby incorporates Defendants' Motion for Partial Summary Judgment and related filings on issues relating to the FUL in the City of New York, et. al v. Abbott Laboratories, et. al., 01-12257-PBS, Dockets 6052, 6053, and 6054, and the Affidavit of Cesar A. Perales; the Affidavit of Dr. Sumanth Addanki, and the Declaration of Kim B. Nemirow Transmitting Deposition Testimony and Hearing Transcripts Relied Upon in Support of Defendants' Joint Motion for Summary Judgment on The United States' "FUL Fraud" Claims. (Reid Decl., Ex. 206-208, 293-295.)

The United States' Response: Dey agreed to withdraw Paragraph 249, as reflected in the parties' Joint Motion For Entry of Additional Briefing Schedule (Docket No. 6252), which was entered by the Court on July 13, 2009.

250. After 2001, in instances where there was a FUL for a drug that was higher than the state MAC, it was Hawaii's practice to reimburse at the higher FUL. This is contrary to Hawaii's State Plan, which provided for reimbursement at "the lower of" billed charges, the provider's usual and customary charge, estimated acquisition cost, FUL or the State MAC. (See Reid Decl., Ex. 209, at 174:4-188:14; Reid Decl., Ex. 210, at 4(a)2.)

The United States' Response: The United States objects to Dey's use of deposition testimony in litigation to which the United States is not a party and did not cross-notice, and where Dey has not produced the transcript or exhibits to the United States notwithstanding an unambiguous discovery request by the United States. The United States further responds that any variance between the State Plan and the State's practice is immaterial. Responding further, the United States does not dispute the quoted language from Hawaii's State Plan, but further responds that the Hawaii practice was and is consistent with the State's regulation. (Henderson Ex. 151; 17 Haw. Adm. R. § 1739.1-2 (2009).) Finally, the United States disputes the 2001 date,

and responds that documentation clearly shows that Hawaii's MAC program was implemented on or about June 1, 2002. (Henderson Ex. 152.)

251. Pharmacy providers must submit the usual and customary charges to states. (See, e.g., Reid Decl., Ex. 192, at 116:4-9; Reid Decl., Ex. 211, at 689:10-13; Reid Decl., Ex. 212, at 70:3-5; Reid Decl., Ex. 142, at 78:16-79:4; Reid Decl., Ex. 198, at 69:17-70:1; Reid Decl., Ex. 213, at 381:15-18; Reid Decl., Ex. 214, at 142:16-143:10; Reid Decl., Ex. 215, at 108:7-12; Reid Decl., Ex. 195, at 220:1-7; Reid Decl., Ex. 216, at 55:21-56:3; Reid Decl., Ex. 145, at 96:7-14; Reid Decl., Ex. 217, at 133:12-14; Reid Decl., Ex. 218, at 108:15-109:3; Reid Decl., Ex. 219, at 237:11-15; Reid Decl., Ex. 220, at 145:19-146:12; Reid Decl., Ex. 146, at 427:19-22; Reid Decl., Ex. 221, at 147:15-22; Reid Decl., Ex. 196, at 61:2-3; Reid Decl., Ex. 222, at 183:2-5, 185:17-20; Reid Decl., Ex. 223, at 228:10-20; Reid Decl., Ex. 224, at 86:4-16; Reid Decl., Ex. 225, at 53:7-10; Reid Decl., Ex. 148, at 299:16-19; Reid Decl., Ex. 149, at 67:11-17; Reid Decl., Ex. 150, at 255:14-15; Reid Decl., Ex. 226, at 309:19-310:1; Reid Decl., Ex. 227, at 246:10-14.)

The United States' Response: The United States does not dispute Dey's SOF No. 251.

252. While usual and customary charges are always submitted by providers, there is variation amongst states' definitions of usual and customary. For example, Alabama Medicaid's provider manual defines "usual and customary charges" as an "[a]mount which a provider usually and most frequently charges patients for a specific service in normal medical circumstances." (Reid Decl., Ex. 228.)

The United States' Response: The United States does not dispute Dey's SOF No. 252.

253. The Virginia Department of Medical Assistance Services' provider manual, appendix A, defines "customary charge" as "[t]he amount providers usually bill patients for furnishing particular services or supplies." (Reid Decl., Ex. 229.)

The United States' Response: The United States does not dispute Dey's SOF No. 253.

254. Massachusetts defines "usual and customary charge" as "the lowest price that a pharmacy charges or accepts from any payer for the same quantity of a drug on the same date of service, in Massachusetts, including but not limited to the shelf price, sale price, or advertised price of an over-the-counter drug." (See 130 Mass. Code Regs. 406.402 (2009).)

The United States' Response: The United States does not dispute Dey's SOF No. 254.

255. Pharmacy providers must verify/certify that the usual and customary charges they submit are accurate. (See, e.g., Reid Decl., Ex. 212, at 74:3-6; Reid Decl., Ex. 198, at 158:10-159:5; Reid Decl., Ex. 214, at 120:11-14, 125:11-127:15; Reid Decl., Ex. 217, at 53:18-54:6; Reid Decl., Ex. 218, at 318:8-11; Reid Decl., Ex. 220, at 66:20-67:10; Reid Decl., Ex. 146, at 210:9-13; Reid Decl., Ex. 224, at 87:9-88:6; Reid Decl., Ex. 149, at 80:7-18; Reid Decl., Ex. 150, at 258:4-259:2, 268:3-8.)

The United States' Response: The United States does not dispute Dey's SOF No. 255.

256. The Government has not contended that the usual and customary charge submitted by the providers are in any way fraudulent. (Reid Decl., Ex. 230.)

The United States' Response: The United States does not dispute Dey's SOF No. 256.

257. Reimbursements are made at the pharmacists' usual and customary charge if it is lower than the other available reimbursement benchmarks, including Dey's published WAC and AWP. (See 42 C.F.R. § 447.512(b) (2009).)

The United States' Response: The United States does not dispute Dey's SOF No. 257 as a general matter, but notes that some Medicaid claims data may show some anomalies.

258. For the states for which Dr. Bradford had state-level claims data, approximately, 10.2 percent of claims for the Subject Drugs for which there is claims data in the record are reimbursed on the basis of the provider's usual and customary charge. (Bradford Decl., Figure 5.)

The United States' Response: The United States does not dispute Dey's SOF No. 258.

259. Each state also includes a state-specific dispensing fee in their reimbursement methodology. (See 42 C.F.R § 447.512 (2009); See 42 C.F.R § 447.514 (2009).)

The United States' Response: The United States does not dispute Dey's SOF No. 259.

260. Dispensing fees differ by state. (Reid Decl., Ex. 33, at 586:10-21.)

The United States' Response: The United States does not dispute Dey's SOF No. 260.

261. The revised AWPs for Dey's albuterol and cromolyn were also circulated to state Medicaid agencies. (Reid Decl., Ex. 231; Reid Decl., Ex. 232.)

The United States' Response: The United States does not dispute Dey's SOF No. 261, assuming that "the revised AWPs" refers to the pricing information referenced in Reid Decl. Ex. 231.

262. The DOJ AWPs were rejected by many states, in whole or in part. (Reid Decl., Ex. 233; Reid Decl., Ex. 232, at ii.) However, at least 18 states chose not to use these lower prices that were recommended and made available to them. Even among the 30 states that actually used these lower revised-AWPs for reimbursement purposes, many expressed skepticism that they will lead to any long-term savings. (Reid Decl., Ex. 232, at ii.)

The United States' Response: The United States does not dispute that 20 states did not elect to use the DOJ AWPs in their reimbursement formalae. (Henderson Common Ex. 24, ¶ 21.) Further answering, the phrase "expressed skepticism that they will lead to any long term savings" is ambiguous as used in the third sentence of this paragraph. The paragraph is otherwise disputed, and is not supported by the cited authority.

263. Cody Wiberg, former pharmacy program manager for Minnesota Medicaid, sent an e-mail to a listserve for National Medicaid Pharmacy Administrators on June 22, 2000 relating to the revised AWPs proposed by NAMFCU in which he stated: "Almost everyone who is familiar with pharmacy reimbursement knows that AWP "Ain't What's Paid". That's why most states and private pharmacy benefit managers reimburse pharmacies at AWP minus a discount (anywhere from 5-15% or more). It is also one reason why there is a federal upper limit list and why many states and private PBMs have maximum allowable cost programs. The spread between AAC and AWP is taken into account when determining what to pay for a dispensing fee." (Reid Decl., Ex. 233, at 2.)

The United States' Response: The United States disputes Dey SOF 263 on the ground that it constitutes inadmissible hearsay. The documents is clearly an out of court statement offered by Dey for the truth of the matters stated therein. Further, the declarant obviously had no

apparent authority to speak on behalf anybody, much less "most states and private pharmacy benefit managers" or the federal government. Accordingly, the statements should be disregarded.

264. Mr. Wiberg's e-mail continued: "Some public and private third part payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquisition cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation." (Reid Decl., Ex. 233, at 2.)

The United States' Response: See the United States' response to paragraph 264 above.

265. Dey only reports one set of prices for publication nationwide yet states have separate and vastly different payment rates for Dey's Subject Drugs. (Stiroh Figures A-K; Reid Decl., Ex. 35, at 433:8-449:12).

The United States' Response: The United States disputes that states have "vastly different" payment rates. Federal regulations require that state Medicaid programs' payment for drugs not subject to Federal Upper Limits not exceed, in the aggregate, the estimated acquisition cost of the drug plus a reasonable dispensing fee established by the agency. 42 C.F.R. § 447.331. "Estimated acquisition cost" ("EAC") is defined by regulation as the state Medicaid agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301. Virtually all states use a "lower of" reimbursement methodology that provides for payment based on the lower of EAC, FUL, or SMAC plus a dispensing fee, or the usual and customary charge ("U&C"). (Henderson Common Ex. 24, ¶ 18.) The United States does not dispute that states have some leeway in how they reach an EAC, and

that states use either AWP minus a certain percentage, or WAC plus a set percentage, or both. The United States asserts that although the reimbursement amounts may differ, these methodologies are more alike than different. All states use a computerized Medicaid Management Information System ("MMIS")[2] and their specific algorithm for adjudicating and reimbursing claims is programmed into the computer. All states rely on one of the pricing compendia for pricing information for the tens of thousands of NDCs reimbursed under their programs.

266. Harry Leo Sullivan, the former Pharmacy Director of the Tennessee Medicaid program, testified that he and other states knew that AWP was not an actual acquisition cost:

Q. During the entirety of the time that you were the director of pharmacy services for Tennessee Medicaid, did you believe that the AWPs in the compendia were a reliable source of information regarding what pharmacies or physicians actually paid for drugs?

A. No.

Q. And from your interactions with other state pharmacy administrators, in your view did other state pharmacy administrators believe that AWPs were a reliable source for what pharmacies and physicians actually paid for drugs?

MR. DRAYCOTT: Objection.

A. Again, I don't ever remember such a specific discussion with, with those peers, because it just wouldn't come up. I – everybody knows the sky's blue. I mean it is that basic to me. I couldn't imagine some -- one of your peers in that situation

[2] In October 1972, Public Law 92-603 was enacted in which Section 235 provided for 90-percent Federal financial participation (FFP) for design, development, or installation, and 75-percent FFP for operation of state mechanized claims processing and information retrieval systems approved by the Secretary. For Medicaid purposes, the mechanized claims processing and information retrieval system which states are required to have, unless this requirement is waived by the Secretary, is the MMIS. An implementing regulation, 45 CFR 250.90, was published May 20, 1974, and subsequent reorganization and clarification of this regulation have been made with the current regulation contained in 42 CFR 433, subpart C.

sitting down and saying, Hey, Did you know pharmacists really aren't paying AWP?

Q. So just as the sky, just as everyone knows the sky is blue, you think your peers knew that average wholesale prices did not represent a reliable source of the prices at which physicians and pharmacies actually paid for drugs.

A. That's correct.

(Reid Decl., Ex. 148, at 98:4-99:9.)

The United States' Response: The United States does not dispute that Mr. Sullivan gave the quoted testimony. Dey has accurately, but selectively, quoted from that deposition. The United States disputes the relevance of the testimony to Dey's liability under the FCA, however, since there was abundant testimony from state Medicaid officials that they did not approve Dey's conduct of reporting inflated AWPs and WACs, that they were unaware of the magnitude of the spreads, and that they considered such conduct fraudulent. (Henderson Ex. 141 (Alaska), at 318-326; Ex. 129 (Illinois) at 76-78; Ex. 139 (Maryland) at 303-304; Ex. 153 (Nebraska) at 375-377; Ex. 154 (New Hampshire) at 241-242; Ex. 155 (New Mexico) at 325-328; Ex. 156 (Washington) at 141-144.)

267. Ingredient reimbursement formulas vary from state to state, and have varied over time within states. As stated by Mr. Scully, "[d]ifferent states had different purchasing arrangements, obviously different dispensing fees, different mixes…different prices…different formularies." (Reid Decl., Ex. 33, at 586:10-18.)

The United States' Response: The United States incorporates its response to ¶ 265. The United States disputes the relevance of this information to Dey's liability under the FCA.

268. Cody Wiberg, former Pharmacy Program Manager for Minnesota's Medicaid program, testified to the diversity of state Medicaid programs: "one of the things you have to understand is, in addition to AWP being 'ain't what's paid,' another common saying that

we have was if you've seen one Medicaid Pharmacy Program, you've seen one Medicaid Pharmacy Program." (Reid Decl., Ex. 196, at 199:5-10.)

The United States' Response: The United States incorporates its response to ¶ 265. The United States disputes the relevance of this information to Dey's liability under the FCA.

269. As seen in the charts attached to the Bradford Declaration, the choices made by states result in a variety of payments based on a variety of bases. (See Bradford Decl., Figures 4, 5, 49).

The United States' Response: The United States incorporates its response to ¶ 265. The United States disputes the relevance of this information to Dey's liability under the FCA.

270. Because of this flexibility, each state Medicaid program is able to weigh various unique local considerations and, as a result, often make different choices when deciding on prescription drug reimbursement rates. (Reid Decl., Ex. 234, at 78:3-22, 136:11-137:8, 156:18-158:6, 161:18-162:8, 163:14-164:4; Reid Decl., Ex. 235, at 763:10-764:11; Reid Decl., Ex. 217, at 34:15-35:4, 38:4-39:16; Reid Decl., Ex. 192, at 140:13-141:1; Reid Decl., Ex. 146, at 142:5-143:10.)

The United States' Response: The United States incorporates its response to ¶ 265. The United States disputes the relevance of this information to Dey's liability under the FCA. The United States disputes the apparent implication that State Medicaid agencies approve Dey's practice of reporting falsely inflated pricing information for the purpose of increasing Medicaid payments.

271. The reimbursement rates each state Medicaid program selects are the result of deliberate policy choices among these components driven by negotiations with or legal action from pharmacy groups, complying with legislative mandates, and ensuring Medicaid recipients have access to services by providing sufficient spread between a provider's acquisition cost and whatever formula a state chooses so that providers remain in the program. (See, e.g., Reid Decl., Ex. 226, at 99:9-100:7, 38:3-9, 40:20-41:5, 196:4-17, 202:4-10, 224:18-225:14; Reid Decl., Ex. 196, at 50:10-18, 111:5-14, 136:7-22, 171:9-172:18; Reid Decl.,

Ex. 217, at 38:4-41:4, 121:2-122:3, 122:14-124:12; Reid Decl., Ex. 192, at 51:4-52:21, 226:4-14; Reid Decl., Ex. 236, at 64:10-65:30, 145:3-146:17; Reid Decl., Ex. 237, at 124:7-125:6; Reid Decl., Ex. 238, at 188:18-189:9, 190:22-191:11; Reid Decl., Ex. 239, at 228:16-234:21; Reid Decl., Ex. 240, at 351:15-353:2; Reid Decl., Ex. 241, at 175:6-176:25; Reid Decl., Ex. 242, at 186:9-187:2, 190:21-25, 224:4-15; Reid Decl., Ex. 234, at 169:8-22; Reid Decl., Ex. 146, at 51:8-53:14; Reid Decl., Ex. 148, at 167:16-170:2; Reid Decl., Ex. 142, at 150:17-153:17; Reid Decl., Ex. 198, at 136:12-137:2, 138:8-140:2, 148:10-150:12, 257:3-21.)

The United States' Response: The United States incorporates its response to ¶ 265. The United States disputes Dey's characterization and the relevance of this information to Dey's liability under the FCA, since there is abundant testimony from state Medicaid officials that their programs and reimbursement formulas were designed to comply with the law and regulations, doing the best they could with an imperfect flow of information from pharmaceutical manufacturers, and relying on published prices to process the multiple thousands of claims submitted. (Henderson Ex. 126 (Arkansas) at 69-70; Ex. 157 (California) at 94-95, 209-210; Ex. 158 (Colorado) at 307-310; Ex. 138 (Delaware) at 379-380; Ex. 129 (Illinois) at 62-64; Ex. 153 (Nebraska) at 341; Ex. 131 (New Jersey) at 134-136; Ex. 159 (Rhode Island) at 112-114.) There was also abundant testimony that states made decisions about dispensing fees separate from setting the reimbursement for ingredient costs, and that they did not approve of manufacturers' reporting inflated prices so that Medicaid programs would pay higher reimbursement for ingredient cost "so that providers remain in the program." (Henderson Ex. 157 (California) at 93-94; Ex. 128 (Georgia) at 76-77; Ex. 129 (Illinois) at 61; Ex. 153 (Nebraska) at 370-372); Ex. 159 (Rhode Island) at 240-241.) Moreover, access to care did not influence reimbursement rates for ingredient costs and was not even a consideration in all states. (Henderson Ex. 160 (New Jersey) at 228:11 - 229:10.)

272. States do not always follow the formulas they have adopted. (Bradford Decl., Figure 5.)

The United States' Response: The United States does not dispute that in rare instances a few States have not implemented the reimbursement formulas adopted by the State. For example, and as noted by Myers and Stauffer in its summaries (Henderson Common Ex. 24, Attachment 1), in Florida an erroneous computer programming change inadvertently bypassed the WAC+7% reimbursement methodology from July 3, 2000, through April 30, 2002. The United States disputes any implication that such occurrences are common or that they are material to the issues in this case.

273. State Medicaid programs have generally reimbursed for the ingredient cost of each drug based on the lowest of the EAC as set by the states, the MAC set by the state, the FUL, or the providers' usual and customary charge, or other state-specific bases. (Reid Decl., Ex. 226, at 77:11-16; Reid Decl., Ex. 243; Reid Decl., Ex. 192, at 31;14-18, 37:2-21; Reid Decl., Ex. 244; Reid Decl., Ex. 245.)

The United States' Response: The United States does not dispute Dey's SOF No. 273 in general, but notes that a number of states do not have MAC programs, and Dey's reference to "other state-specific bases" is ambiguous and therefore disputed. (Henderson Common Ex. 24.)

274. For those states that base EAC on AWP, EAC is calculated as AWP less a percentage. (Reid Decl., Ex. 226, at 279:9-13, 72:19-73:4, 77:17-20; Reid Decl., Ex. 246, at WA-00001282; Reid Decl., Ex. 243; Reid Decl., Ex. 247; Reid Decl., Ex. 248; Reid Decl., Ex. 192, at 31:14-18, 37:2-21; Reid Decl., Ex. 249; Reid Decl., Ex. 234, at 169:4-7, 333:17-334:1, 385:7-11; Reid Decl., Ex. 250; Reid Decl., Ex. 251.)

The United States' Response: The United States does not dispute Dey's SOF No. 274.

275. Forty-one states require generic substitution because it is generally cheaper than the brand. (Reid Decl., Ex. 196, at 257:12-258:7; Reid Decl., Ex. 217, at 72:3-22, 73:6-12, 74:1-21, 155:15-156:13, 157:3-7; Reid Decl., Ex. 192, at 67:10-68:3; Reid Decl., Ex.

252, at 571:22-573:7; Reid Decl., Ex. 238, at 134:8-135:10, 142:10-15; Reid Decl., Ex. 239, at 112:5-13; Reid Decl., Ex. 234, at 93:2-13; Reid Decl., Ex. 148, at 60:12-61:14, 62:13-63:10; Reid Decl., Ex. 253, at 2.)

The United States' Response: The United States does not dispute Dey's SOF No. 275.

276. Most states have chosen to calculate EAC based on a discount from AWP, but some have relied on WAC pricing data. (See, e.g., Reid Decl., Ex. 245; Reid Decl., Ex. 270, at 604:11-21; Reid Decl., Ex. 238, at 34:15-35:1.)

The United States' Response: The United States does not dispute Dey's SOF No. 276.

277. Still others have used one benchmark only to switch to another benchmark at a different point in time, such as Florida (WAC pricing to AWP-based reimbursement and back to WAC). (Reid Decl., Ex. 245; Reid Decl., Ex. 254; Reid Decl., Ex. 255.)

The United States' Response: The United States does not dispute Dey's SOF No. 277, except that "still others" is ambiguous and therefore disputed. (Henderson Common Ex. 24.)

278. Furthermore, some states have frequently revised the discount on AWP or the percentage added to WAC and others have chosen not to revise the calculation or modify it only rarely. Alaska has maintained its EAC at AWP-5% since 1990, and Minnesota has modified its EAC formula four different times in the span of about ten years, from AWP-10%, AWP-14%, AWP-11.5% and then to AWP-12%. (Reid Decl., Ex. 234, at 169:4-7, 333:17-334:1, 385:7-11; Reid Decl., Ex. 243; Reid Decl., Ex. 256; Reid Decl., Ex. 257; Reid Decl., Ex. 196, at 130:9-131:10.)

The United States' Response: The United States does not dispute Dey's SOF No. 278.

279. States routinely impose MACs or rely on FULs for particular drugs as a way to control costs, and Dey's Subject Drugs were frequently subject to such caps. (Reid Decl., Ex. 211, at 505:1-17; Reid Decl., Ex. 258, at 352:24-353:2; Reid Decl., Ex. 146, at 47:18-22, 151:2-10; Reid Decl., Ex. 142, at 99:16-102:12.)

The United States' Response: Dey's use of the words "routinely" and "frequently" are ambiguous and therefore disputed. The United States does not dispute that States implement FULs, and a number of States implement MACs.

280. Some states, including Georgia and New Hampshire, establish MAC prices based on a proprietary formula by a contractor. (Reid Decl., Ex. 259, at 66:11-67:10; Reid Decl., Ex. 198, at 207:3-209:2.)

The United States' Response: The United States does not dispute Dey's SOF No. 280.

281. Other states, including Arkansas, Tennessee, and Washington surveyed providers about their invoice or actual acquisition costs. (Reid Decl., Ex. 148, at 106:18-109:19; Reid Decl., Ex. 192, at 65:3-11, 244:14-246:1; Reid Decl., Ex. 226, at 265:12-266:9, 238:17-22; Reid Decl., Ex. 260, at 37:12-38:11, 59:16-20.)

The United States' Response: The United States does not dispute Dey's SOF No. 281.

282. States did surveys, set MACs, and received Dey's letters regarding Dey's WAC and AWP. (Reid Decl., Ex. 226, at 105:9-107:13, 135:3-10, 211:21-212:6; Reid Decl., Ex. 261; Reid Decl., Ex. 262; Reid Decl., Ex. 196, at 246:5-247:2; Reid Decl., Ex. 263; Reid Decl., Ex. 217, at 148:8-149:18; Reid Decl., Ex. 238, at 145:22-146:14; Reid Decl., Ex. 193, at 204:16-20; Reid Decl., Ex. 264, at 74:16-19, 76:3-11; Reid Decl., Ex. 234, at 168:1-169:2; Reid Decl., Ex. 265, at 355:15-357:5; Reid Decl., Ex. 146, at 331:5-21; Reid Decl., Ex. 142, at 218:4-219:21; Reid Decl., Ex. 198, at 268:15-271:19.)

The United States' Response: The United States incorporates its response to No. 148 above insofar as Dey SOF #282 asserts that States received Dey's letters. The United States does not dispute that some States did surveys, and some States set MACs.

283. States regularly met with each other and shared information. (Reid Decl., Ex. 260, at 72:1-19, 97:8-21; Reid Decl., Ex. 196, at 148:5-152:16; Reid Decl., Ex. 259, at 60:22-61:19; Reid Decl., Ex. 266, at 857:25-859:9; Reid Decl., Ex. 267, at 735:5-19, 736:20-23; Reid Decl., Ex. 235, at 529:20-531:2.)

The United States' Response: The United States does not dispute Dey's SOF No. 283. The United States disputes the relevance of this information to Dey's liability under the FCA.

284. Delaware's 30(b)(6) designee, Cynthia Denemark, testified that Delaware has understood since at least 1993 that AWP does not reflect a providers' actual acquisition cost, but

nonetheless Delaware continues to rely on AWP as one possible basis for reimbursement in order to cross-subsidize Delaware's inadequate dispensing fee. (See Reid Decl., Ex. 142, at 268:1-269:3.)

The United States' Response: The United States disputes that Dey has accurately characterized the cited deposition testimony. The United States does not dispute that the witness testified she understood since 1993 that AWP didn't reflect actual acquisition cost. Reid Exhibit 143 at 268:1-269:4. The witness also testified that she would never have told a pharmaceutical manufacturer that she approved of reporting inflated AWP's because she is not of the opinion that "it is a reasonable thing to have an inflated AWP," and it is "a sad commentary on the profession that we have no data element that we can reliably use for ingredient costs. . . ." (Henderson Ex. 138, at 485:1-486:13.)

285. The United States' damages expert, Dr. Mark Duggan, submitted an expert report in this case which analyzed claims data for 14 states. However, even for those states, he is not solely relying on detailed claims data to calculate differences. (Reid Decl., Ex. 270; Bradford Decl. ¶ 28.)

The United States' Response: The United States disputes this SOF. Dr. Duggan's report analyzed claims data consisting of (1) State Drug Utilization Data ("SDUD") for 48 states, which is derived from state claims data, (2) SMRF/MAX/MSIS data for 48 states, which is claims level data obtained from States by CMS containing over 40 data elements including, for example, the NDC, the date of service, the charged amount, the paid amount, the date of the payment, and the quantity; and (3) claims data for 14 states obtained in connection with the instant litigation. (Reid Decl. Ex. 270, Tables 11, 12A, 12B; Henderson Common Ex. 41 (Duggan Decl.).) The United States does not dispute that Dr. Duggan did not rely solely on one particular data set to calculate damages for any given State.

286. Claims data was available for 32 states. (Bradford Decl. ¶ 25.)

The United States' Response: Disputed. See Response 285 above.

287. SDUD is aggregate data containing the state, the NDC, the name of the drug, the total units reimbursed for that quarter, the total number of prescriptions for the quarter, the total amount reimbursed for that NDC for the quarter, and quarter covered. (Reid Decl., Ex. 268; Bradford Decl. ¶ 26.)

The United States' Response: Undisputed.

288. MAX/SMRF data has some claims-level data, but it is not available for all states prior to 1999, and does not include quantity for any state prior to 1996. (Reid Decl., Ex. 269; Bradford Decl. ¶ 27.)

The United States' Response: Undisputed; but see the United States' response to No. 285 above.

289. MAX/SMRF also does not include dispensing fee and co-payments, which reduces the precision of attempts to calculate the reimbursement basis. (Bradford Decl. ¶ 27.)

The United States' Response: The United States does not dispute this, but states that the dispensing fee and co-payment amounts were effectively quantified by Dr. Duggan in his calculations and there was no material reduction of precision.

290. MAX/SMRF data is also rounded, which further reduces the precision of payment basis analysis. (Bradford Decl. ¶ 27.)

The United States' Response: The United States does not dispute that dollar values in the MAX/SMRF data are rounded to the nearest dollar; however, but since it is reasonable to expect that half are rounded up and half are rounded down it is unlikely for there to be any material

impact. (Henderson Common Ex. 41 (Duggan Decl. ¶ 15).)

291. Pricing arrays have not been produced for all DMERCs-quarters at issue. Dr. Duggan has extrapolated his 'difference' calculations for quarters with missing pricing arrays. There are many idiosyncratic variations in pricing array across DMERCs and over quarters, thus making a straightforward extrapolation problematic. (Bradford Decl., ¶¶ 34, 35.) Furthermore, Dr. Duggan calculates differences for some arrays where the DMERCs did not include Dey's NDCs. (Bradford Decl., ¶¶ 34, 35.)

The United States' Response: The United States disputes Dey's SOF No. 291. All available pricing arrays have been produced. The United States does not dispute that pricing arrays for a few DMERC-quarters do not exist. The United States disputes that "there are many idiosyncratic variations" in pricing arrays, and further notes that, for ipratropium bromide, all DMERCs calculated the same allowable amount for K0518/J7644 prior to January 1, 1998 ($3.52 per unit), and for K0518/J7644 for the period January 1, 1998, through December 31, 2003 ($3.34, which is 95% of $3.52). Any variations in pricing arrays were properly considered by Dr. Duggan. Dr. Duggan does not calculate Dey damages for arrays where the DMERCs did not include Dey NDCs; in those quarters his calculations result in zero damages for Dey. (Henderson Ex. 96.)

292. Dr. Duggan testified that his basis for creating joint "differences" scenarios for Dey and Roxane is that both had been sued by the Government. (Reid Decl., Ex. 291 at 434:1-7).

The United States' Response: The United States disputes this Statement as misleading because it ignores the fact that Dr. Duggan clearly determined the joint impacts of Dey and Roxane because both defendants reported false prices that were used in the arrays and in many

arrays the false prices combined to create a joint impact on the Medicare reimbursement amount greater than the sum of the individual impacts.

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "RESPONSE OF THE UNITED STATES OF AMERICA TO DEY DEFENDANTS' STATEMENT OF

UNDISPUTED MATERIAL FACTS IN SUPPORT OF DEY, INC., DEY, L.P., AND DEY L.P., INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II

Dated: July 24, 2009

George B. Henderson, II